

# EXHIBIT 40

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

IN THE MATTER OF )

IN RE BAIR HUGGER FORCED AIR )  
WARMING )  
PRODUCTS LIABILITY LITIGATION )

Plaintiff, )

v. )

3M COMPANY AND ARIZANT )  
HEALTHCARE INC. )

Defendant. )

)PRETRIAL ORDER NO: 7  
)Protective Order  
)MDL No. 15-2666  
) (JNE/FLN)

DEPOSITION OF PAUL MCGOVERN

VOLUME I

Wednesday, January 4, 2017

AT: FAEGER BAKER DANIELS

Taken at:

7 Pilgrim Street  
London EC4V 6LB  
United Kingdom

Court Reporter: Louise Pepper

Videographer: Simon Addinsell

Job No: 117119

A P P E A R A N C E S

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1 DR. PAUL MCGOVERN

2 P R O C E E D I N G S

3 THE VIDEOGRAPHER: This is the beginning of DVD 1  
4 in volume 1 of the deposition of Dr. Paul McGovern in the  
5 matter of the litigation for In Re Bair Hugger Forced Air  
6 Warming Products Liability Litigation. This matter is in  
7 the United States District Court, the District of Minnesota,  
8 and the number is MDL 15-2666(JNE-FLN). Today's date is  
9 4 January 2017 and the time is currently a quarter to  
10 10 a.m. The deposition is taking place at the offices of  
11 Faeger Baker Daniels in London. The court reporter is  
12 Louise Pepper, the videographer Simon Addinsell, both with  
13 TSG. Can we just go off the recording a second? I'm  
14 getting bad interference.

15 (9:45 a.m.)

16 (Off the record.)

17 (9:46 a.m.)

18 THE VIDEOGRAPHER: Back on the record at 9:46 of  
19 the read-in. Could counsel in the room please introduce  
20 themselves and say who they are representing today, please.

21 MR. C. GORDON: Corey Gordon on behalf of  
22 defendant, 3M company.

23 MS. NEWMAN: Katherine Newman on behalf of 3M.

24 MR. HEAD: Andrew Head, partner at Forsters, on  
25 behalf of Dr. McGovern.

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2 MR. SACCHET: Michael Sacchet on behalf of the  
3 plaintiffs.

4 MS. ZIMMERMAN: Genevieve Zimmerman on behalf of  
5 the plaintiffs.

6 THE VIDEOGRAPHER: Could the court reporter please  
7 swear the witness in now, please.

8 PAUL MCGOVERN  
9 having been sworn testified as follows:

10 THE VIDEOGRAPHER: It's 9:47, you're on the  
11 record. Please begin, counsel.

12 EXAMINATION BY MR. C. GORDON

13 BY MR. C. GORDON:

14 Q. Good morning, Dr. McGovern.

15 A. Good morning.

16 Q. We met briefly before. I'm Corey Gordon; I  
17 represent 3M company in connection with proceedings in the  
18 United States involving litigation over the 3M Bair Hugger  
19 warming product. Have you ever had your deposition taken  
20 before?

21 A. No.

22 Q. Have you ever given testimony in court?

23 A. No.

24 Q. Okay. The main thing that makes this different  
25 than a normal conversation is we have a court reporter

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2 taking down testimony. So that means a couple of things.  
3 Number one, a nod or a shake of the head, which would  
4 communicate something to me, can't be transcribed. So if  
5 you would try to remember to answer "yes", "no", whatever,  
6 verbally as opposed to a shake or nod of the head.

7 The other important thing is that I have to wait  
8 for you to finish your answer before I begin another  
9 question. You have to wait until I'm done with the  
10 question completely before you begin your answer.

11 Again, just so the court reporter is able to cleanly  
12 transcribe what is being said. Sometimes that gets  
13 a little uncomfortable because in normal human  
14 communication we talk back and forth, and often times  
15 will start answering before somebody finishes,  
16 et cetera.

17 You are here today originally pursuant to an  
18 agreement that was worked out between the parties; is  
19 that your understanding?

20 A. Yes.

21 Q. And as part of that agreement, both the plaintiffs  
22 and the defendants have agreed to pay your attorneys' fees  
23 and to reimburse you for the time you have spent preparing,  
24 and the time you are here giving testimony; is that your  
25 understanding?



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2 A. Yes.

3 Q. Does the fact that your time is being paid for, or  
4 your attorneys' time is being paid for, the fact that it is  
5 being paid for jointly by the parties to these proceedings,  
6 the plaintiffs and the defendant, do you think that in any  
7 way influences your testimony?

8 A. I do not.

9 Q. And as part of the agreement, you undertook to  
10 collect certain documents that we had requested; is that  
11 correct?

12 A. Yes.

13 Q. We're going to -- just to get the administrative  
14 stuff out of the way, we're going to go through and identify  
15 on the record and formally mark the multiple volumes of  
16 documents that are seated before you, and then hopefully get  
17 at least some of them out of the way while we ask the  
18 questions. But I'm going to start with the first one that  
19 we marked, which is volume 1A, or exhibit 1A. And if you  
20 could just tell us just briefly what that is.

21 (Exhibit 1A marked for identification)

22 A. This appears to be a record of e-mails that I have  
23 sent and received in relation to this matter.

24 Q. And by "this matter", you're talking about  
25 generally the activities that you have been involved in that

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2 relate to the Bair Hugger?

3 A. Correct. So it --

4 THE VIDEOGRAPHER: Sorry, can I stop you. Your  
5 microphone, sir. It is inside your jacket. Thank you.  
6 Okay, sorry about that.

7 A. Where were we?

8 THE VIDEOGRAPHER: I beg your pardon.

9 A. Where were we?

10 BY MR. C. GORDON:

11 Q. The e-mails that relate to the Bair Hugger.

12 A. Yes. So they are e-mails that were sent and  
13 received by me in relation, generally, to research that  
14 I have done into the Bair Hugger system, and also into  
15 infection, or the potential for infection, in operating  
16 rooms.

17 Q. Okay, and yesterday we received from your attorneys  
18 a set of indices. I'm going to show you what I've marked as  
19 exhibit 1B. Is that now the index to what we've marked as  
20 1A?

21 (Exhibit 1B marked for identification)

22 MR. HEAD: Can I clarify, is 1A and 1B what we  
23 call 1 and 2?

24 MR. C. GORDON: No. This is going to get  
25 confusing. Exhibit 1A is the documents itself, the folder

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2 with the -- it's your volume 1 of 2.

3 MR. HEAD: Right. That's the e-mails, yes?

4 MR. C. GORDON: Of the e-mails.

5 MR. HEAD: Right.

6 MR. C. GORDON: 1B I've marked -- what I've marked  
7 as just the index itself.

8 MR. HEAD: Of the e-mails?

9 MR. C. GORDON: Of exhibit 1A, of just volume 1 of  
10 2 of the e-mails. I know it's going to get confusing.

11 A. I haven't cross-correlated all of these, but this  
12 appears to be representative of the e-mails that I've sent.

13 BY MR. C. GORDON:

14 Q. I'm guessing that was sent by your counsel's  
15 office?

16 A. The?

17 Q. The index.

18 A. Yes.

19 (Exhibit 2A marked for identification)

20 Q. The next thing I've marked is 2A. That would be  
21 the second volume of e-mails you collected relative to this  
22 matter; is that right?

23 A. Yes, yes.

24 (Exhibit 2B marked for identification)

25 Q. Similarly, then, 2B would be the index; is that

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2 right? The index for what we've marked as exhibit 2A?

3 A. Yes.

4 Q. Okay. Now, I believe those are the -- those two  
5 volumes, exhibits 1A and 2A, comprise the e-mails that you  
6 collected and produced in connection with this; is that  
7 correct?

8 A. Yes.

9 Q. Let's stop for one moment and briefly -- what were  
10 your search parameters? How did you go about collecting  
11 these e-mails?

12 A. I looked through the -- these e-mails are from my  
13 personal e-mail account, which draws in e-mails from some of  
14 the work e-mails that I've had over the period of time in  
15 question. I searched based on who the correspondence was  
16 with, and the idea of that search was to catch any relevant  
17 e-mails. I can't remember the exact search terms I used. I  
18 have provided them at some point. So I searched for words  
19 which would have -- mainly names of correspondents which  
20 would have been included in this discussion.

21 Q. Did you ever use an e-mail account in connection  
22 with an employment situation, or otherwise, that was not  
23 searched as part of this?

24 A. I may have used my e-mail account for the NHS,  
25 which is the UK National Health Service, for some of the

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2 correspondence. However, the vast majority of my  
3 correspondence, and I suspect all correspondence, would have  
4 been on this e-mail account, to the best of my knowledge.  
5 My practice is to try to keep things in one account, and so  
6 while people will have e-mailed me while I was working for  
7 Northumbria Healthcare Trust on my NHS e-mail account, which  
8 is now inactive and I don't have access to, it is very  
9 unlikely that any significant amount of correspondence will  
10 have been on other accounts, although it is possible.

11 Q. Before we go any further, let's just get an  
12 overview of your background. You are a physician; is that  
13 correct?

14 A. That's correct.

15 Q. When did you complete your medical training?

16 A. I qualified my -- I qualified as a doctor in 2006.

17 Q. And at that point did you do what we would call a  
18 residency?

19 A. So in the UK doctors will undertake two years of  
20 foundation training in which they are registered as doctors  
21 and they are working as doctors. And that, I think, would  
22 correspond to an internship. And then I moved into surgical  
23 practice, which I think corresponds to a residency, in  
24 what's termed basic, and then -- basic for two years and  
25 then higher surgical training in trauma and orthopedics.

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2 Q. So your -- first of all, where did you get your  
3 medical degree?

4 A. UCL, University College London.

5 Q. That first two years of foundation training, where  
6 was that done?

7 A. That was in the North Central Thames Foundation  
8 School, which is an organization which administers and  
9 provides junior level doctors to hospitals, and my first  
10 year of training was in Basildon, B-A-S-I-L-D-O-N, Hospital  
11 in Essex just outside London. And my second year was in  
12 University College Hospital in Central London.

13 Q. And where did you begin your orthopedic training?

14 A. My basic surgical training, so --

15 Q. -- just need your surgical training.

16 A. Well, they're the same thing. Orthopedic training  
17 and basic surgical training, they are the same program.  
18 I started in the northern regions, so around Newcastle in  
19 the North of England, and I started working in Durham on  
20 a two-year basic surgical training program administered  
21 centrally in the North East of England, which saw me go to  
22 various hospitals in various different training programs. I  
23 worked in Durham Hospital for eight months, working in  
24 trauma and orthopedics for four months and then plastic  
25 surgery for four months, and then I worked in a hospital in

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2 Stockton Upon Tees for four months in general surgery and  
3 breast cancer surgery, and oncoplastic surgery. Then I  
4 worked in Wansbeck Hospital in Ashington in Northumberland  
5 to the north of Newcastle for six months, and then I was in  
6 the University Hospital of -- North Tees or North  
7 Tyneside? -- I think North Tyneside -- for another six  
8 months.

9 Q. And Wansbeck is part of the Northumbria Trust?

10 A. That's correct. So the whole of that second year  
11 of basic surgical training, even though I was in two  
12 different hospitals, both hospitals are part of Northumbria  
13 Healthcare NHS Trust.

14 Q. Both Wansbeck and North Tyneside?

15 A. Yes.

16 Q. So what year would you have started doing anything  
17 in north --

18 A. 2009 to 10.

19 Q. And when you were through with your higher training  
20 in trauma and orthopedics --

21 A. Yeah, that was my basic trading. So you have two  
22 years of foundation training, two years of basic training,  
23 and then six years of higher training.

24 Q. Okay. Where was the six years of higher training?

25 A. So I haven't completed -- I've since changed

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2 specialties, so I'm no longer in trauma and orthopedics, but  
3 after finishing in Northumbria Healthcare I worked at UCL  
4 Medical School as a teaching fellow and lecturer for eight  
5 months, that was a post split between Basildon Hospital in  
6 Essex and UCL Medical School. And then after that, I  
7 entered higher surgical training for the South London or  
8 South East Thames Region for that, for orthopedic higher  
9 surgical training.

10 Q. Was that at a particular hospital?

11 A. So that was Princess Royal University Hospital in  
12 South London for six months, and then Medway Hospital in  
13 Gillingham, Kent, for two years.

14 Q. At what point did you decide to switch  
15 specialities?

16 A. So, after two years in Medway Hospital in  
17 Gillingham, I became a lecturer again at UCL Medical School  
18 in post-graduate medical education and education  
19 consultancy, and that was initially for a single-year post  
20 out of my training program as a programmed or approved  
21 activity -- the intention to be to return to orthopedic  
22 training. But that role was extended, and during that  
23 period I changed specialty to occupational medicine. So  
24 I worked for three years for UCL Medical School in  
25 post-graduate education and medical education consultancy,



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2 and started working as an occupational physician/trainee, or  
3 occupational physician, in August 2016.

4 Q. Still at University College London?

5 A. No, that for a company called Medigold Health or  
6 Medigold Healthcare.

7 Q. That's a private company?

8 A. Correct.

9 Q. Not associated with the National Health Service?

10 A. Correct.

11 Q. How long will your program be in occupational  
12 medicine?

13 A. That's a four-year training and working while  
14 training program.

15 Q. And when you complete that, you would be  
16 a specialist in occupational medicine?

17 A. That's correct. The plan will be to complete that  
18 training and become a specialist. That would be, to my  
19 understanding, an attending-level occupational physician or  
20 a consultant. Occupational physician, as we'd say in the  
21 UK.

22 Q. When was the last time you performed any orthopedic  
23 surgery? Or maybe where?

24 A. It would be Medway in Kent, was the last time  
25 I performed any orthopedic surgery.

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2 Q. Is Medway part of a trust?

3 A. That is, I think, Medway NHS Foundation Trust.

4 I think that's the name of the trust.

5 Q. And when you were at Medway, did you perform any  
6 hip or knee joint replacements?

7 A. Yes.

8 Q. What type of warming, patient-warming systems were  
9 being used at Medway when you were there?

10 A. The type of warming systems used at Medway at the  
11 time I was there were Bair Huggers. And while I was there,  
12 there was a period of looking at other warming devices, one  
13 of which was HotDog, and another one was I think  
14 a conductive warming technology that was not HotDog. It was  
15 from a different company, but I don't remember the name of  
16 it.

17 Q. Is that possibly Indotherm?

18 A. It may have been Indotherm. The blankets were  
19 orange, as I remember. But it may have been another  
20 company.

21 Q. As a result of the -- that period of looking at the  
22 other warming devices, did -- while you were there, did  
23 Medway switch to a different device?

24 A. I don't know if they formally and finally switched.  
25 There was a period when they were using other devices, but I

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2 don't know if the hospital or the trust made a whole scale  
3 or a wholesale switch to a different device or different  
4 technology. I don't know.

5 Q. And when you left there, was Bair Hugger still  
6 being used for arthroplasties?

7 (Reporter clarification.)

8 A. I don't remember.

9 Q. Okay. So, let's go back to 2009 when you started  
10 at Wansbeck. Was that the first time you would have had any  
11 contact with Mr. Mike Reed?

12 A. Yes. Err ... no. Any contact whatsoever would  
13 probably have been in 2008 because he is -- or was -- fairly  
14 senior in the training of -- involved in the training of  
15 orthopedic surgeons in the northern deanery. So it is  
16 likely I would have received e-mails from him prior to 2009,  
17 probably in 2008. They would have been not to me  
18 personally; they would have been group e-mails. I don't  
19 remember the content of them, but it is likely I would have  
20 had received communication from him before then, but the  
21 first time that I started working with him was in 2009.

22 (Reporter clarification.)

23 Q. What month in 2009 did you start at Wansbeck?

24 A. August.

25 Q. Using that as kind of a benchmark time frame, when

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2 you started at Wansbeck in August 2009, had you had any  
3 involvement in any activity or attending any seminar,  
4 reading any material, anything that would have raised any  
5 questions about the use of forced-air warming of Bair Hugger  
6 in orthopedic surgery?

7 A. I don't remember.

8 Q. Now, certainly subsequent to the time you started  
9 at Wansbeck, something got you involved in, and  
10 interested in, forced-air warming?

11 A. Yes.

12 Q. What was -- do you recall what it was that first  
13 attracted your interest?

14 A. As a training surgeon, there is -- one is  
15 encouraged to undertake audit activity and research  
16 activity. And so it's common practice for a surgical doctor  
17 to speak to their boss, their consultant, or someone senior  
18 to them, to ask if any research is ongoing in the  
19 department. And one of Mike Reed's research interests is  
20 infection in the operative or the perioperative period. And  
21 in fact, it's something that is taken very seriously in all  
22 hospitals, in all orthopedic departments, but Wansbeck --  
23 there was a culture in the department of being very vigilant  
24 for possible sources of infection to -- with a view to  
25 reducing overall infection rate.

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2 And so I was introduced to the research in  
3 question by Mike Reed, following an approach from  
4 myself to get involved with some research that was  
5 ongoing in the department.

6 Q. When you started in August of 2009 at Wansbeck,  
7 were you aware of any concerns that the NHS had expressed  
8 about the rate of infections in the orthopedics department  
9 at the -- in the Northumbria Trust hospitals?

10 A. I was not there that the NHS had expressed any  
11 concerns.

12 Q. And as you sit here today, you never heard that  
13 there had been concerns expressed about how high the rates  
14 of infection had been?

15 A. So, you say the NHS. What I took to mean by that  
16 was the higher body of the NHS. I wasn't aware if they had  
17 particularly expressed concerns. However, I was aware that  
18 there were concerns within the department that the infection  
19 rate at that trust was higher than would have been  
20 considered ideal, and there were efforts to bring it down.

21 Q. And when you started, were -- had all those efforts  
22 to bring it down already been undertaken, or were there  
23 still some efforts that were ongoing or yet to be  
24 implemented?

25 MR. SACCHET: Object to form.

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2 (Reporter clarification.)

3 MR. C. GORDON: That's actually a good objection.  
4 I'll rephrase the question.

5 BY MR. C. GORDON:

6 Q. When you started in August 2009, are you aware of  
7 steps that had already been taken prior to August 2009 to  
8 reduce the infection rates at those hospitals, the  
9 Northampton Trust hospitals?

10 A. I was not aware of steps at the time.

11 Q. Okay. Subsequent to your starting there in  
12 August 2009, were you aware of any steps that were taken or  
13 procedures that were implemented, practices that were  
14 implemented, to attempt to reduce the infection rate?

15 A. There's a constant and ongoing effort, in any  
16 responsibly-run surgical department, to reduce infection  
17 rates, particularly in orthopedics. And so it's not  
18 a question, to my recollection, that there was a period  
19 where there weren't steps to reduce infection rates, and  
20 subsequent change. There are always efforts to reduce  
21 infection in orthopedics departments. So I don't remember  
22 a specific time when practice was -- where one could draw  
23 a line in the sand. I don't remember a specific time when  
24 that was. My recollection is of a department that was  
25 always trying to reduce infection rates.

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2 Q. We'll come back to that soon, in some detail,  
3 later. So, when you started in August 2009, Mike Reed was  
4 your supervisor?

5 A. Yes.

6 Q. And you asked him what kind of research he was  
7 doing that you might become involved in; is that fair?

8 A. Yes.

9 Q. And what was the first thing that he involved you  
10 in?

11 A. The first thing I remember is -- was a discussion  
12 about infection rates and a project to investigate the  
13 possibility of infection, or the possibility of  
14 a Bair Hugger influencing bacterial load in an operating  
15 room, possibly increasing infection rates.

16 Q. And what was your understanding of how that  
17 research issue had arisen? Because that's -- what was the  
18 genesis of it, to your understanding?

19 A. Sorry, could you repeat the question?

20 Q. As I understand it, you asked Mr. Reed: "What  
21 research can I get involved in?"

22 And he said: "We're looking at Bair Hugger and its  
23 possible impact on influencing the bacterial load."

24 Do you know how that it came to be that that was  
25 a -- that was something that Mr. Reed was looking at?

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2 A. No, I don't know how that specifically came to be.

3 Q. At any time, had you -- strike that.

4 When you talk about the bacterial load, could  
5 you explain what you mean?

6 A. Yes. So, an operating room is a clean environment  
7 and one in which the presence of any possible source of  
8 infection to the patient must be reduced so far as is  
9 possible. And when I say bacterial load in this specific  
10 case, what I refer to are particles in the air which may  
11 have bacteria on them. Generally, these include dust  
12 particles from the patient, from circulating theater staff  
13 and the scrubs team, skin cells, water droplets or moisture  
14 droplets from exhaled air from the surgical team, from the  
15 patient, from the process of surgery. All particles which  
16 may be in the air which may themselves carry bacteria which  
17 have the potential to settle in an operative wound and the  
18 potential to cause infection.

19 Q. Is it the bacteria that actually causes the  
20 infection, or the particles?

21 A. The bacteria causes the infection. The particles  
22 are the vector for the infection, and so the bacteria will  
23 stick to particles. They are all around us right now. The  
24 air is loaded with particles anywhere you are, unless you  
25 have a device or an environment which is specifically



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2 controlled to reduce the count of airborne particles.

3 Q. Do all particles carry bacteria?

4 A. No.

5 Q. Is there some generally accepted rule of thumb as  
6 to what percentage of particles carry bacteria?

7 A. Not that I'm aware of, because it depends on the  
8 situation. It depends on the environment.

9 Q. So, in an operating room, if there are particles  
10 present, they may or may not carry bacteria?

11 A. Correct.

12 Q. And if particles that don't carry bacteria settle  
13 on the surgical wound, do they increase the risk of  
14 infection?

15 A. If particles that don't carry bacteria settle on  
16 the surgical wound, do they increase the chance of  
17 infection? Potentially, yes, but that's not something  
18 which -- potentially, yes.

19 Q. How would a bacteria-free particle potentially  
20 increase the risk of infection?

21 A. It could cause irritation. If a particle were  
22 toxic, if it were -- if it caused a reaction in the patient,  
23 to the patient's immune system, then that could cause  
24 inflammation and -- which could contribute to infection,  
25 because excess of inflammation can reduce the body's ability

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2 to fight infection. So in itself it would not cause  
3 infection, but it could create or assist the creation of  
4 a condition which could increase predisposition to  
5 infection. However, it's very unlikely.

6 Q. So when you speak of bacterial load in connection  
7 with this initial research activity that you became involved  
8 in, was the focus on transmission of actual bacteria that  
9 would -- that could be settled, or that could settle on the  
10 operative site?

11 A. So ... just repeat the question, please?

12 Q. It was a very poorly phrased question. I'll  
13 rephrase it.

14 In your initial research activities at  
15 Wansbeck under Mr. Reed where you looking at bacterial  
16 load and the impact of the Bair Hugger, is it correct  
17 to say that the bacterial load you're talking about is  
18 actual bacteria that could potentially be transmitted  
19 to the operative site?

20 A. Initially, we looked at -- we attempted to measure  
21 bacteria directly, as well as indirectly. So we've used  
22 particles, airborne particles, as a model or as -- almost as  
23 a way of measuring potential for infection. Initially we  
24 did an experiment which attempted to pick up or detect  
25 bacteria -- excuse me -- as well as attempting to detect

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2 particles in the air.

3 Q. At this point I'm going to stop and go back to my  
4 administrative tasks of identifying the other documents you  
5 brought so that we -- when you start, because I'm going  
6 to -- I can see we're going to start referring to them  
7 fairly quickly. And I think we are up to 3A, which I'm  
8 going to mark here.

9 (Exhibit 3A marked for identification)

10 In addition to the two volumes of e-mails  
11 that you have produced for us, there are -- your  
12 attorneys produced eight volumes of additional  
13 materials, and I am going to start with what I've  
14 marked as exhibit 3A, which I believe is identified as  
15 volume 1 of documents produced by Dr. Paul McGovern,  
16 that we received from your attorneys. And just to  
17 match things up here, I'm going to give you exhibit 3B,  
18 which I understand is the exhibit to exhibit 3 -- or  
19 excuse me, the index to exhibit 3A.

20 (Exhibit 3B marked for identification)

21 A. Right.

22 Q. I don't want to take a lot of time, you know, going  
23 through each of the documents in detail; I just want to get  
24 a general sense of what the document -- what that document  
25 folder consists of.

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2 A. This consists of documents which I retrieved from  
3 my computer systems and from my e-mail record which were  
4 related to this research.

5 Q. Were all these retrieved electronically, or did you  
6 have any hard copies?

7 A. I did not have any hard copies. All of these were  
8 retrieved electronically.

9 Q. I'm assuming at least some of them were attachments  
10 to the e-mails?

11 A. Yes. So the -- there are two groups of documents.  
12 Some will be repeated. The strategies I used to retrieve  
13 the documents was to attach, or to provide any attachments  
14 to the e-mails, and I've also separately trawled hard drives  
15 of various computers that I've had since 2009/10 and  
16 identified the files which were related to this and provided  
17 them, as well.

18 Q. And to that point, there are often multiple copies  
19 of the same document?

20 A. That's correct. It would have been extremely time  
21 consuming to go through and identify, to cross-correlate  
22 each version to ensure there were no duplicates. I thought  
23 it was not an efficient use of time, given the time  
24 constraints, and so I provided all the files which were  
25 referred to in the e-mails and, as well, in my hard drive.

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2 So by the very nature of it, some of them will be  
3 duplicated.

4 Q. So, as I understand it, when -- every e-mail that  
5 you collected that had an attachment, you also included the  
6 attachment in these documents volumes?

7 A. Correct, correct.

8 Q. Okay. And I think the next one is -- I'm going to  
9 mark as 4A. And if you want to use that chair next to you  
10 to start moving stuff over ... just so you don't get buried  
11 in too much stuff. Could you tell us what 4A is?

12 (Exhibit 4A marked for identification)

13 A. 4A appears to be further files that I've retrieved,  
14 either via e-mail or via trawling my own computers, which  
15 those files are related to this matter, this research.

16 Q. And this was produced by your attorneys and labeled  
17 as volume 2?

18 A. Mm-hm.

19 Q. Yes?

20 A. Yes.

21 Q. Okay. The sequencing, and whether it is volume 2  
22 or 1, I'm assuming that was done by your attorneys, not you?

23 A. Yes.

24 (Exhibit 4B marked for identification)

25 Q. Okay. And exhibit 4B, that is the index to 4A; is

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2 that right?

3 A. Yes.

4 (Exhibit 5A marked for identification)

5 Q. I'm going to show you 5A. Is that volume 3 of the  
6 document you pulled together?

7 A. Yes.

8 (Exhibit 5B marked for identification)

9 Q. Okay. And is exhibit 5B the index to that?

10 A. Yes.

11 (Exhibit 6A marked for identification)

12 Q. We're getting there. 6A, that's your volume 4 of  
13 the documents you've collected?

14 A. Yes.

15 (Exhibit 6B marked for identification)

16 Q. And volume 6B -- or excuse me, exhibit 6B, is the  
17 index to volume -- the volume we've marked as 6A. Is that  
18 correct?

19 A. I think you've given me two.

20 Q. Sorry.

21 A. Yes.

22 (Exhibit 7A marked for identification)

23 Q. And the next is -- sorry, I put the exhibit sticker  
24 on upside down. Exhibit 7A is volume 5 of the documents you  
25 collected; correct?

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2 A. Yes.

3 (Exhibit 7B marked for identification)

4 Q. And exhibit 7B is the index to the volume we've  
5 marked as exhibit 7?

6 A. Yes.

7 (Exhibit 8A marked for identification)

8 Q. And exhibit 8A, that would be your volume 6 of the  
9 documents you've collected; is that right?

10 A. Yes.

11 (Exhibit 8B marked for identification)

12 Q. And exhibit 8B is the index to exhibit 8A; correct?

13 A. Correct.

14 (Exhibit 9A marked for identification)

15 Q. Almost done. Exhibit 9A, that would be your  
16 volume 7 of the documents you collected; is that right?

17 A. Yes.

18 (Exhibit 9B marked for identification)

19 Q. And exhibit 9B would be the index to the document  
20 which was marked as exhibit 9A; is that right?

21 A. Yes.

22 (Exhibit 10A marked for identification)

23 Q. And finally exhibit 10A. That will be the volume  
24 that the -- the eighth and final of the volumes you  
25 collected and your attorneys produced; is that right?

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2 A. Yes.

3 (Exhibit 10B marked for identification)

4 Q. And exhibit 10B would be the index to exhibit 10A?  
5 Is that right?

6 A. Yes.

7 Q. All right. Let's start with exhibit 10A.

8 MR. HEAD: Is it all volume 8?

9 MR. C. GORDON: It is volume 8, right. If you  
10 want to turn to the page numbered 3541. It looks like this  
11 particular document goes through page 3552; is that right?

12 A. Yes.

13 Q. And the cover page identifies this as "Bair Hugger  
14 Study, Wansbeck Hospital, Ashington 28/11/09"?

15 A. Yes.

16 Q. For those of us across the Atlantic, that would be  
17 November 28, 2009?

18 A. Yes.

19 Q. So can you tell us what this document is, or what  
20 it reflects?

21 A. This is a draft write-up of an experiment conducted  
22 at Wansbeck Hospital, which attempted to -- well, which  
23 examined the influence of Bair Hugger systems in a laminar  
24 flow operating room.

25 Q. Were you involved in any of the underlying research



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2 activities that are discussed in this document?

3 A. Yes.

4 Q. And were you involved in the drafting of this  
5 document?

6 A. Yes.

7 Q. Okay. Was anyone else involved in the drafting?

8 A. They were. I think that this version -- yeah,  
9 other people were involved in the drafting of this. Yes.

10 Q. Maybe this will help clear it up one way or the  
11 other. Turn to page 3615, please.

12 A. Yeah.

13 Q. And this is a document that's titled "DO FORCED AIR  
14 WARMING DEVICES INCREASE BACTERIAL CONTAMINATION OF  
15 OPERATIVE FIELD? - Simulated experimental analysis."

16 And then there are several names listed there.

17 Is this -- the document 3615, is this concerning  
18 the same experiment that is reflected in the document  
19 that starts at 3541?

20 A. It is.

21 Q. Okay. So I see a series of names at the top of  
22 3615?

23 A. Yes.

24 Q. Are these other individuals, people who  
25 participated in some way in the -- either the conduct of the

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2 experiment or the writing of it?

3 A. Yes.

4 Q. And there are it looks like six names listed?

5 A. Correct.

6 Q. You're the first name listed.

7 A. Correct.

8 Q. Who was the second person?

9 A. Dr. Shreya Srinivas.

10 Q. And who was he or she?

11 A. She was a senior -- or well, a more senior  
12 orthopedic trainee than myself. So another trainee level  
13 surgeon who was, I don't know how many years senior to me,  
14 but -- not an attending level, but a more senior trainee.

15 Q. And how about the next person listed?

16 A. The next -- I can't remember the first names. They  
17 were both male, name P. Sutaria and D. Bull. They were  
18 junior doctors, I -- yeah, they were doctors who were  
19 working in the department who were junior to me.

20 Q. Were they orthopedic trainees?

21 A. I don't remember.

22 Q. And the next name?

23 A. Valerie Edwards-Jones, a professor of microbiology.

24 Q. The University of Manchester?

25 A. It may have been the University of Manchester. It

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2 may have been Manchester Metropolitan University. They were  
3 two separate institutions. I think she was from Manchester  
4 but I can't remember the institution.

5 Q. Actually Manchester?

6 A. Manchester Metropolitan.

7 Q. Metropolitan.

8 A. Yeah.

9 Q. MMU?

10 A. That's the one. That rings a bell.

11 Q. Did you ever meet Professor Edwards-Jones?

12 A. I did.

13 Q. And the last name there is?

14 A. Mike Reed.

15 Q. And we refer to him as "Mr. Mike Reed"?

16 A. Mr. Mike Reed.

17 Q. Because he is a ...

18 A. Surgeon.

19 Q. Fully accredited senior surgeon?

20 A. Yes.

21 Q. This is really weird to us, from the United States.

22 A. I can be "Mr. McGovern" as well, because I have  
23 that surgical qualification too. It is archaic.

24 Q. If we were to call a doctor in the United States  
25 Mr. or Ms., it would be the slap in the face. But we've

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2 learned. All right.

3 So -- can you think of any other people that  
4 were involved, directly or indirectly, in either the  
5 development and design of a protocol for the study, the  
6 implementation of this study, or the drafting of this  
7 study?

8 A. Not that I can remember.

9 Q. Did you ever meet Dr. David Leaper, Professor David  
10 Leaper?

11 A. I did. I have met Dr. David Leaper.

12 Q. Do you know if he had any involvement in this?

13 A. I've met Dr. David Leaper and he ... he introduced  
14 me to the particle counter that was used in this study and  
15 told me what it was.

16 Q. Do you recall the name of that particle counter?

17 A. Handilaz.

18 Q. When you say introduced you to it, he brought the  
19 unit to Wansbeck and showed you how to use it, or?

20 A. He didn't show me how to use it. He had a flight  
21 case with it in, in a meeting, and said "See if you can work  
22 out how to use it," I think.

23 Q. Okay. Was that Handilaz particle counter something  
24 that was capable of identifying bacteria?

25 A. No.

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2 Q. What steps, if any, were incorporated in the  
3 protocol to identify bacteria?

4 A. This experiment used two methods to attempt to  
5 identify bacteria. Both centered around bacterial plates,  
6 that is plastic dishes with a substance on them which  
7 encourages the growth of bacteria, such that when bacterias  
8 settle on the plates and they are incubated for an  
9 appropriate time in an appropriate environment, bacterial  
10 growth occurs which allows the identification of bacteria  
11 having formed on the plate three days previously.

12 Two methods that were used were to put plates in  
13 various positions around the operating room. Different  
14 plates contained different materials or different media  
15 to isolate different strains of bacteria, and these were  
16 placed around the room with the lids off, so that if any  
17 bacteria settled on them, they would be identified.  
18 That was one method.

19 The second method was using a device which is  
20 designed to draw air over the plate, so to ingest air  
21 from the surrounding environment and deposit it on the  
22 bacteria -- bacterial growth plate. So both those  
23 methods were used in this experiment.

24 Q. Did you ever hear the terms "active" and "passive  
25 sampling" in connection with these two techniques?

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2 A. They sound familiar. I don't remember if they  
3 were -- those specific words were used, but that is what  
4 I understand these types of sampling to be. The former,  
5 which I described, would be passive, and the latter would be  
6 active.

7 Q. The settle plates would be the passive?

8 A. That would be my understanding. Although I don't  
9 recall if that was the terminology used at the time.

10 Q. What was your understanding of why the two  
11 different techniques were incorporated?

12 A. The -- there's only one device to draw air over  
13 a settle plate, and that device -- there's a certain amount  
14 of -- the chances of a bacterium, a single cell landing on  
15 a settle plate, are low. And active sampling allows the  
16 sampling of a larger volume of air than a settle plate does.

17 Q. Do you recall any discussion as to whether floating  
18 bacteria that didn't settle is of less concern from  
19 a surgical infection standpoint than bacteria that do  
20 settle?

21 A. Could you repeat the question, please?

22 Q. I will ask the question. Have you read any  
23 literature that discusses the pluses and minuses of using  
24 a settle-plate technique as opposed to an active-sampling  
25 technique?

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2 A. At the time I had, but I haven't since 2009.

3 Q. Do you remember the -- any kind of a discussion or  
4 debate, if you will, as to whether it mattered more for  
5 surgical site infections if it was something that was  
6 airborne and collected by active sampling versus something  
7 that settled out on a settle plate?

8 A. Right. So the -- these are techniques to  
9 investigate if bacteria are in the environment, and the  
10 sampler, the active sampler, was placed in a region that was  
11 as close as we could get it to a simulated operating site.  
12 So it was appropriate that that sampled a larger amount of  
13 air because that was the -- seemed to be the most important  
14 area. That is to say that bacteria in that area would be  
15 the least desirable from a surgical point of view because  
16 bacteria anywhere else -- if bacteria don't get into the  
17 operating field, into the operating site, that is the most  
18 important thing to avoid. And so that is the area that was  
19 looked at, the focus of the investigation in that part  
20 of it, and that's why the sampling unit was placed near the  
21 simulated operating site.

22 Q. Were there any settle plates also placed near the  
23 simulated operating site?

24 A. I don't remember. They may have been -- no, I  
25 don't remember.

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2 Q. Okay.

3 A. They were placed in the room, but I don't remember  
4 if they were placed near the operating site.

5 Q. It's not a memory test. So I am wondering if the  
6 document we've been looking at that starts at page 3541  
7 helps you recall where the settle plates were placed?

8 A. Yes. That's right. So the air-sample plates from  
9 this method were -- the sampling plates were placed closest  
10 to the operating site and the settle plates were further  
11 away.

12 Q. Okay. And I think you're looking at page 3543?

13 A. I am.

14 Q. And it looks like there's something labeled "ASL"  
15 and then something labeled "ASR"?

16 A. Yes.

17 Q. What are those?

18 A. Those are the positions that the air-sample plates  
19 were put in, in relation to the simulated patient.

20 Q. And that's that active air sampler?

21 A. Correct.

22 Q. Kind of sucking in air?

23 A. Correct.

24 Q. Were there two samplers, then?

25 A. No, there was one unit and it was moved between



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2 different experiment runs.

3 Q. Okay. And then the other letters on this page 343,  
4 A, B, C, D, E, F, G and H, those represent just the settle  
5 plates?

6 A. That's correct.

7 Q. And those are also called agar plates?

8 A. Agar plates, yeah.

9 Q. Who determined how many settle plates, and where to  
10 locate them?

11 A. The number of settle plates and the precise make-up  
12 was determined by Professor Valerie Edwards-Jones as the  
13 microbiology expert. The position of the settle plates  
14 I will have decided in conjunction with my co-investigators.  
15 The rationale for this is that on this image on the page  
16 3543, is you see a red box surrounding the simulated patient  
17 in the diagram. That red box marks the position of the  
18 laminar flow boundary, laminar flow being a device in the  
19 ceiling of the operating room to minimize or reduce the  
20 likelihood of particles getting into operating fields. The  
21 idea being within that box, ideally bacterial counts would  
22 be lower, and outside they would be higher. And therefore,  
23 the sampling was done in different positions relative to  
24 that boundary zone outside, which are A, B, C and D, and  
25 inside, which are E, F, G and H.

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2 Q. Just so we're clear on what you mean by the red  
3 box, you are talking about the single red line that goes all  
4 the way around the what appears to be a patient?

5 A. Correct.

6 Q. Because there's also a solid red box on the inside?

7 A. The solid red box corresponds to the area on the  
8 simulated patient which was marked out as a simulated  
9 operating field, which is in the photo on page 3544.

10 Q. So that internal solid red box on 3543, that's the  
11 area of concern; that's where you don't want the bacteria,  
12 right?

13 A. Correct.

14 Q. And the active sampling, the ASL and ASR, how far  
15 away from the -- that area of concern, that specific --  
16 I think it is referred to on 3544 as the "sterile field"?

17 A. Yeah, it is. And the distance is -- I can't  
18 measure it, but they were as close as we could get it. And  
19 you can see on the lower image on 3544 the distance that the  
20 air sampler was from the operative field when in position  
21 ASL. When in position ASR, it was on the other side of the  
22 operating table as close as it could be to the patient, but  
23 obviously slightly further away, given the fact that the  
24 patient's left -- or the simulated patient's left leg was in  
25 the way.

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2 Q. As long as we're on 3544 in that lower picture,  
3 there's some sort of an apparatus on the right-hand side  
4 that looks like it's wrapped in plastic?

5 A. Yes.

6 Q. What's that?

7 A. That is the particle counter.

8 Q. And that's the -- is that the Handilaz?

9 A. Yes.

10 Q. And that looks like the -- is that a nozzle of some  
11 sort that actually does the -- that's where the counting is  
12 done?

13 A. That is the intake port for the particle counter.

14 Q. That looks like it is right over the sterile field.

15 A. It is right over the sterile field.

16 Q. And the air sampler, where is the intake for that?  
17 It's in the top, or --

18 A. It's on the top. So that shiny metallic apparatus  
19 on the top is the sampling area. The plate, which is  
20 a disc, fits into that apparatus on the top. The apparatus  
21 is in two parts. The top comes off and the top half is  
22 perforated. So it is a block of metal which is perforated,  
23 and the plates sit in that but the top screws back on, or  
24 fits back on, and air is drawn over the plate through those  
25 holes onto the agar plate.

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2 Q. And on the top picture on 3544 it looks -- there's  
3 something identified as "Settle Plate F"?

4 A. Yes.

5 Q. It looks like that's on the floor?

6 A. That's correct.

7 Q. Is it -- how many plate are there on the floor?

8 A. On that image there are four plates. There may  
9 have been another one out of view. Each -- the groups of  
10 plates are counted as one settle plate because they each  
11 contain different ...

12 Q. Growth media?

13 A. Growth media. Exactly right. So they would  
14 isolate different strains of bacteria.

15 Q. So, on 3543 where it identifies the settle plates A  
16 through G, that's -- each location is actually cluster --

17 A. That's right.

18 Q. -- of five different plates?

19 A. Of however many. I can't remember how many plates  
20 there were, but yeah, that's a cluster.

21 Q. The attempt, the goal there was whatever species of  
22 bacteria might find their way to that particular area, one  
23 of the growth media would pick it up?

24 A. That was the intention.

25 Q. Okay. Now where would the Bair Hugger unit have

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2 been placed during this experiment?

3 A. The Bair Hugger -- you mean the blower or the  
4 blanket?

5 Q. Good question. Let's start with the blower.

6 A. The blower? It doesn't look like we've recorded  
7 where the blower was in this method. Let me check that we  
8 haven't recorded it. The blower was positioned somewhere  
9 near the head end -- oh, no. The head end of the patient,  
10 in all likelihood.

11 Q. Was an attempt -- strike that.

12 When you set up this experimental setting,  
13 was an attempt made to replicate standard operating  
14 protocol as much as possible?

15 A. In some ways, yes. Attempts were made, but in  
16 several ways this did not simulate an operation accurately.  
17 So we attempted to simulate it as accurately as possible,  
18 but on reflection, there are some areas which are not  
19 consistent with what you'd normally expect in an operation.

20 Q. Can you list those areas of inconsistencies?

21 A. First, there were far fewer personnel in the  
22 operating room than there would be in a usual operation.  
23 As -- yeah. There was at most, to my recollection, one  
24 person within the laminar-flow boundary at any one time that  
25 was the simulated surgeon, which is very unrealistic.

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2 Second, the simulated patient was not positioned for any  
3 common operation. They were not positioned for a hip  
4 replacement or for a knee replacement. They were draped in  
5 a way which would be reasonable, were someone to access the  
6 front of the thigh, but the number of operations requiring  
7 that would be very low. And the result of that is that the  
8 way the simulated patient was set up was not representative  
9 of virtually all real operations, specific -- particularly  
10 hip or knee arthroplasty procedures.

11 There were no trays of equipment in the  
12 operating room. And the position of the lights, your  
13 overhead operating lights, was not recorded and it was  
14 not consistently controlled for. So, while it is  
15 likely that the overhead operating lights were moved  
16 out of the way for convenience, their position was not  
17 accurately recorded and it was not necessarily kept  
18 consistent between experimental runs, although there is  
19 no reason why they would have been moved. But it  
20 wasn't something which was taken into consideration  
21 during the experimental design.

22 Q. Was the laminar flow system on?

23 A. The laminar flow system was on.

24 Q. And the patient there, is that a real person or  
25 a mannequin?

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2 A. That's a real person. It was one of the  
3 co-investigators.

4 Q. One of the people junior to you?

5 A. Absolutely. Well, in this image it is. I was on  
6 that table at points of it, but I don't remember if it was  
7 for these experimental runs or if it was when we were  
8 setting up.

9 Q. Okay. Getting back to the location of the  
10 Bair Hugger, would it have been within the -- the fan  
11 unit -- within or without the laminar flow curtain?

12 (Reporter clarification.)

13 Q. Or the laminar flow boundary, I should say?

14 A. Based on the information here, there's no way of  
15 knowing.

16 Q. What would have been the standard practice?

17 A. Standard would have been to have it within the  
18 laminar flow boundary. However, this schematic on page 3543  
19 may not -- is not to scale, and so may not accurately  
20 reflect the distance between the head end of the patient and  
21 the -- that corresponding laminar flow boundary. In  
22 practice, it is not uncommon for the head end of the patient  
23 to be very close to the laminar flow boundary because of the  
24 anesthetic equipment, because the operating table needs to  
25 be positioned appropriately for both the operation and for

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2 the position of the anesthetic equipment. And so there is  
3 every possibility that that operating table in real -- in  
4 the experimental set-up would have been closer to the  
5 corresponding laminar flow boundary relating to the head end  
6 of the patient. That's why I can't say with certainty  
7 whether the blower unit for the forced-air warming device  
8 was within or outside, or on the boundary level of the  
9 laminar flow zone, because it depends how the operating room  
10 was set up and I -- we did not record that in this  
11 experiment.

12 Q. Okay. Where was the Bair Hugger blanket itself?

13 A. The Bair Hugger blanket was in the yellow position  
14 marked on page 3543 over the torso of the simulated patient.

15 Q. Was that under the torso or over the torso?

16 A. Over the torso.

17 Q. And the perforated holes out of which the warm air  
18 is blown, that would have been facing down towards  
19 the patient?

20 A. That would have been down towards the patient. The  
21 Bair Hugger was positioned on the patient, as would be usual  
22 practice for an operation. The Bair Hugger has an adhesive  
23 strip -- one or more adhesive strips on it, depending on the  
24 design of the blanket, and they correspond to the correct  
25 orientation of the warming blanket. And so those blankets



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2 were put on with the adhesive strip facing downwards, as  
3 would be standard practice for them.

4 Q. Was there any additional draping on top of the Bair  
5 Hugger?

6 A. Yes. So, as can be seen in the image on 3544,  
7 standard sterile surgical drapes were positioned over the  
8 patient and over the Bair Hugger blanket, as would usually  
9 be the case for an operation.

10 Q. So at least in terms of where the Bair Hugger  
11 blanket was positioned and how it was set up and draped,  
12 that was done in accordance with standard procedure; is that  
13 correct?

14 A. Yes.

15 Q. Where would any heat that wasn't being transferred  
16 to the patient go from the -- from a blanket?

17 A. Heat energy would be transmitted to the drape over  
18 the patient and to the areas surrounding the blanket. And  
19 so that would -- any leaked heat would -- any energy from --  
20 any heat energy which did not go into the patient would go  
21 into the surrounding environment.

22 Q. And was there anything different about where the --  
23 that excess heat energy went, in this experimental set-up,  
24 than would have been the case in a real surgery?

25 MR. SACCHET: Object to form.

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2 A. Repeat the question, please?

3 BY MR. C. GORDON:

4 Q. However the heat energy that wasn't transferred to  
5 the patient escaped into the surrounding environment, was  
6 there anything different about that in this experimental  
7 set-up than would have been the case in an actual surgery?

8 MR. SACCHET: Object to form.

9 A. What sort of surgery?

10 BY MR. C. GORDON:

11 Q. Well, I guess any surgery where an upper-body torso  
12 blanket was used.

13 A. So, were a surgery taking place on the front  
14 portion of a patient's thigh, and were it draped in exactly  
15 this way, then the -- any heat dissipation would be the same  
16 or similar to that found in this -- in this set-up. The  
17 differences are in the interaction of the -- of any heat  
18 with the environment, because there is a suction unit --  
19 there are two suction units next to the operative field, one  
20 for the bacterial plate and one for the particle counter,  
21 although the airflow through the particle counter is low.  
22 And there would be a difference in the environment, as  
23 previously described, with regards to the number of site  
24 staff around the area.

25 Q. In an actual surgery, in addition to staff, there

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2 would be other requirement that would be generating --

3 A. Yeah.

4 Q. -- heat and air currents; right?

5 A. Generating heat, not so much. Surgical tools do  
6 exist which generate heat, absolutely. Air currents,  
7 generating air currents: again, a human will generate air  
8 currents by moving, but the air current will be disrupted or  
9 altered by other equipment in the area.

10 Q. There's a presence of a -- a mass in an airstream?

11 A. Yeah, depending on its location within the  
12 airstream and depending on its location with relation to  
13 other objects nearby.

14 Q. Do you ever -- did you ever have occasion to use  
15 fiberoptic light?

16 A. I have in my practice.

17 Q. And I'm talking about the headlamps.

18 A. The headlamps.

19 Q. Where is the light source for those headlamps?

20 A. The light source is -- you're attached through  
21 fiberoptic cable to a box which stands at least 3 feet  
22 behind the user.

23 Q. Does that box generate any heat?

24 A. Does the?

25 Q. The fiberoptic light box generate --

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2 A. That does generate heat, yes.

3 Q. Does it have any kind of fan inside it to dissipate  
4 the heat?

5 A. Depending on the design, some do.

6 Q. Okay. Back to this experiment. So who was present  
7 when the experiment was actually conducted?

8 A. Myself, Dr. Bull, Dr. Sutaria,  
9 Professor Edwards-Jones, and occasionally Mr. Reed. He was  
10 on site and would pop in, but he wasn't there throughout the  
11 entire experiment -- experimental undertaking.

12 Q. How many times was the experiment run?

13 A. I don't remember.

14 Q. I think -- I'm at 3541 -- it says "The experiment  
15 was run 4 times" at the bottom.

16 A. Four times.

17 Q. Is that consistent with your recollection?

18 A. I don't recall how many times it was run, but  
19 I've written "4 times" and so that's --

20 (Reporter clarification.)

21 A. It was run -- I didn't say "three or four".  
22 I don't recall what happened, but I've written "4 times" and  
23 so that is ...

24 Q. Was that four times over the course of one day?  
25 Multiple days?

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2 A. I don't remember.

3 Q. Do you recall approximately how long each run took?

4 A. The runs are recorded. I believe each run took 30  
5 minutes.

6 Q. And in sort of general terms, what you were looking  
7 at was about the number of particles and the bacteria with  
8 and without the Bair Hugger on; is that correct?

9 A. Yes.

10 Q. And you described a null hypothesis. For the  
11 benefit of the jury, what is the null -- what do you mean by  
12 a null hypothesis?

13 A. A null hypothesis is a way of framing a scientific  
14 investigation such that you have an idea, or a hypothesis,  
15 and you test it, and if -- the null hypothesis is  
16 a condition in which your suspicion or your proposal is not  
17 found to be upheld on the evidence -- on the experiment that  
18 you conduct.

19 Q. So here, where you describe the null hypothesis  
20 being that the use of the Bair Hugger forced-air warming  
21 device results in no particular bacteria or particular  
22 contamination to the operative field, does that mean that,  
23 going into this, what you really were thinking was that the  
24 Bair Hugger warming device was going to result in additional  
25 bacteria or particulate contamination?

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2 MR. SACCHET: Object to form.

3 A. That phrasing implies that the result had been  
4 predicted. This is the -- the scientific purpose of the  
5 investigation was to test that hypothesis. And so the  
6 hypothesis to be tested was whether this experiment provided  
7 an indication that the Bair Hugger in this set-up resulted  
8 in additional bacterial particulate contamination to this  
9 operative field.

10 BY MR. C. GORDON:

11 Q. And I'm sure my questions aren't clear. What I'm  
12 trying to say, going into this experiment, was it your  
13 working assumption that use of the Bair Hugger would  
14 increase particles or bacteria?

15 MR. SACCHET: Object to form.

16 A. The question of whether the Bair Hugger influenced  
17 bacteria or particulate contamination was what was being  
18 tested. And that -- the aim of the experiment, the aim of  
19 the process, was to test that hypothesis.

20 BY MR. C. GORDON:

21 Q. And I'm assuming that the protocol was developed  
22 and designed to be as scientifically robust as the  
23 collective wisdom of the participants could bring to bear?

24 MR. SACCHET: Object to form. Misstates the  
25 evidence.

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2 A. The attempt was -- at the time, the intention was  
3 to make it as robust as possible.

4 BY MR. C. GORDON:

5 Q. And particularly in terms of the microbiological  
6 complement, you worked with a fairly prominent expert in  
7 microbiology, right?

8 MR. SACCHET: Object to form.

9 A. I worked with a Professor of microbiology.

10 BY MR. C. GORDON:

11 Q. And turn to page 3547.

12 A. Yes.

13 Q. There it says:

14 "It was hypothesised that turning on the  
15 Bair Hugger blanket would create warm air currents  
16 that, despite the influence of laminar air flow, would  
17 contaminate the operative field with particles,  
18 possibly including pathogenic bacteria."

19 A. Yes.

20 Q. That's what you were -- that was the working  
21 hypothesis. That's what you're going in to test?

22 A. That's the hypothesis that the intention of the  
23 study was to test.

24 Q. Okay. And one of the things you found was that the  
25 introduction of the surgeon to the vicinity of the field

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2 raises the particle count in the zone of the field?

3 A. That is what this experiment found.

4 Q. And when you talk about the introduction of the  
5 surgeon, does that mean just the surgeon walking up to the  
6 table?

7 A. Yes.

8 Q. Okay. And you also found that that was most marked  
9 when the surgeon touches the disinfected skin within the  
10 field. And you wrote:

11 "It seems reasonable to suppose that these detected  
12 particles represent shed epithelial particles from  
13 the patient."

14 Is that right?

15 A. That's what was written.

16 Q. So how -- what did the surgeon do? He or she  
17 touched the skin with --

18 A. I think a gloved finger. The simulated surgeon  
19 approached the operative field and I think touched, drew  
20 their finger across, the sterilized surgical field with  
21 a hand that was gloved, with a surgical glove.

22 Q. But then you went on to say:

23 "However, there is no suggestion from these  
24 results that turning on the bair hugger makes any  
25 difference to operative field particle counts under



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2 controlled conditions."

3 A. That's what's been said there.

4 Q. So whether the Bair Hugger was on or off didn't  
5 have any impact on the particle counts?

6 MR. SACCHET: Object to form.

7 A. It's actually not possible to say whether it had  
8 any statistically significant influence because the data has  
9 not been statistically analyzed. The data has been  
10 presented but not analyzed.

11 BY MR. C. GORDON:

12 Q. Okay. Then on page 3548, where you are discussing  
13 the microbiology sampling.

14 A. Mm-hm.

15 Q. That would be the sampling for the bacteria, right?

16 A. Correct.

17 Q. And you -- under "Results" it says:

18 "Table 1 shows that there was minimal number  
19 of bacteria isolated from settle plates opened for  
20 4 hrs."

21 A. Yes.

22 Q. "The settle plates from position C showed the  
23 highest numbers of bacteria. There were no fungi isolated."

24 A. Yes.

25 Q. And position C would have been away over in the

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2 corner, outside of the laminar airflow field?

3 A. Correct.

4 Q. Okay. Now on page 3549, the -- you describe the  
5 bacteria that were isolated from the settle plates as  
6 being -- consisting as coagulase negative staphylococci,  
7 diphtheroids and micrococci -- micrococci? Which you  
8 characterize as skin organisms; is that right?

9 A. Yes.

10 Q. Then you wrote:

11 "No [and the "no" is boldfaced] coliforms, MRSA,  
12 staphylococcus aureus, Clostridium difficile, or candida  
13 albicans were isolated. "

14 A. Yes.

15 Q. Why was that significant for you to note the  
16 absence of those?

17 A. Those types of bacteria are particularly relevant  
18 for joint infection. Were an infection with staphylococcus  
19 aureus or MRSA, which is a type of staphylococcus aureus, or  
20 coliforms to find their way into a wound, they can have very  
21 significant consequences. I'm not so sure about the  
22 consequences of clostridium difficile or candida albicans.  
23 That would be less common, but still very concerning if they  
24 found their way into a surgical wound.

25 Q. Okay. The -- another part of this test was that

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2 you actually took the hose of the Bair Hugger and blew that  
3 on to the settle plates; is that right?

4 MR. SACCHET: Object to form.

5 A. Where is that written?

6 BY MR. C. GORDON:

7 Q. Page 3551 at the bottom.

8 A. Yes.

9 Q. And at the very bottom it says:

10 "The air from Bair Hugger 4 (present in the  
11 operating theater) was sampled over a 1 minute period by  
12 blowing air directly onto CBA at 20 second intervals."

13 A. (The witness nodded).

14 Q. What's CBA?

15 A. Yeah, CBA is a growth medium. It's one of the  
16 types of agar plate that is used to isolate and culture  
17 bacteria.

18 Q. And you found no growth of microorganisms; right?

19 A. That's correct.

20 Q. Otherwise none that culture medium -- media did not  
21 catch -- did not show any bugs in the airstream of the  
22 Bair Hugger?

23 A. That's correct.

24 MR. SACCHET: Object to form.

25 BY MR. C. GORDON:

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2 Q. And the ultimate conclusion of the experiment on  
3 page 3552 was:

4 "Settle plates, air sampling, wound sampling, and  
5 swabbing Bair Huggers showed there was only very low  
6 numbers of skin bacteria found within various areas of  
7 the operating theater during the operating procedure if  
8 correct procedures are carried out."

9 Correct?

10 A. That is the conclusion that was written there.

11 Q. Do you know who funded this study?

12 A. No.

13 Q. So, sitting here today, you are unaware that  
14 Augustine --

15 MR. SACCHET: Object to form. Asked and answered.

16 MR. C. GORDON: You may want to wait until I am  
17 done with my question.

18 MR. SACCHET: Yeah, but you've said what --

19 MR. C. GORDON: Yeah, but just out of courtesy you  
20 may to wait until I'm done with before you interpose your  
21 objection. Thanks.

22 BY MR. C. GORDON:

23 Q. To this day, you're unaware that Scott Augustine's  
24 company, at the time in 2009, provided £5,000 of funding to  
25 Mr. Reed and his team to carry out this experiment?

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2 A. I did not know that any money had been provided for  
3 this experiment. I now know that the particle counter was  
4 owned by -- or I believe that the particle counter was owned  
5 by the company, but I did not know that at the time. But  
6 I did not know, until you've just told me, that any money  
7 had been received in relation to this experiment.

8 Q. Okay. If I could ask you to turn to page 3568.  
9 How would you describe this document?

10 A. This is a different write-up of the experiment that  
11 we have been discussing. Yes.

12 Q. So it -- and it looks like this -- the document  
13 that we're talking about goes from page 3568 to 3572; is  
14 that right?

15 A. Yes.

16 Q. So this involves the same experiment?

17 A. Yes.

18 Q. Did you also write this?

19 A. I was involved in the writing of this. I don't  
20 know exactly what proportion of this I wrote. This write-up  
21 went through multiple versions, and so the proportion of  
22 this which was written by me is not something that I can  
23 remember. But I was involved in the writing of this.

24 Q. Do you know which came first, the one we've just  
25 been looking at, or the one we're looking at now?

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2 A. I think, to the best of my recollection, the  
3 version which we have been looking at came first.

4 Q. Okay. And on the version we're looking at now, in  
5 the conclusion on page 3568, the conclusion is that the use  
6 of forced-air warming devices does not increase the  
7 bacterial count in the vicinity of the operative field.  
8 Right?

9 A. That is what is written there.

10 Q. And if that's the case, in other words if you were  
11 to do this experiment in every conceivable configuration and  
12 repeat it multiple times in multiple centers and  
13 consistently find the same results, if the ultimate  
14 conclusion is that forced-air warming devices do not  
15 increase the bacterial counts in the vicinity of the  
16 operative field, that would mean that all the stuff about  
17 convection currents and excess heat and waste heat and all  
18 that other stuff really doesn't mean anything, in terms of  
19 surgical site infection risk; right?

20 MR. SACCHET: Object to form.

21 A. Could you repeat that, please?

22 BY MR. C. GORDON:

23 Q. If the ultimate conclusion is that using  
24 Bair Hugger does not increase the bacteria in the operative  
25 field, then all the other stuff, the bubbles and the smoke

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2 and air currents, none of that matters, does it?

3 MR. SACCHET: Object to form.

4 A. You're saying if Bair Huggers don't increase or  
5 don't have an influence in the levels of bacteria in the  
6 operative field, you're saying that none of that matters.  
7 But I am not quite sure what you're saying.

8 BY MR. C. GORDON:

9 Q. Well, a lot of your subsequent research was in air  
10 currents and movement of bubbles and smoke, and things like  
11 that.

12 A. Yes.

13 Q. But if there's no increase in bacteria as a result  
14 of the use of Bair Hugger, then the Bair Hugger can't be  
15 responsible for increasing the risk of bacterial infections  
16 in surgical sites; right?

17 MR. SACCHET: Object to form.

18 A. Do you mean if Bair Huggers never caused bacteria  
19 to go into surgical sites?

20 BY MR. C. GORDON:

21 Q. Right. If the use of Bair Huggers does not  
22 increase the bacterial count in the vicinity of the  
23 operative field, then anything else it does --

24 A. Well, no, if Bair Huggers don't increase the  
25 bacterial count in the vicinity of the operative field,

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2 that's not the same as Bair Huggers not increasing the  
3 bacterial count in operative fields. There's a significant  
4 difference, or potentially a significant difference, because  
5 the vicinity of the operative field could be a zone an inch  
6 above the operative field. It's a vague -- it's a vague  
7 classification. And what matters is if bacteria find their  
8 way into an operative field and ultimately cause infection.  
9 Bacteria do land in operative fields in different sorts of  
10 operations, but in different operations, the consequences to  
11 the patient are very different. And so the use of  
12 forced-air warming devices not increasing the bacterial  
13 count in the vicinity of the operative field is different  
14 from increasing the bacterial count in the operative field,  
15 or in the operative wound, or on an implant. So they are  
16 related but they are not the same.

17 Q. Did you conduct any experiments to see if the use  
18 of the Bair Hugger increased the bacterial count in the  
19 operative field?

20 A. No.

21 Q. In terms of relevance to the risk of surgical-site  
22 infections, would you agree that bacteria in the vicinity of  
23 the operative field is of greater relevance than particles?

24 MR. SACCHET: Object to form.

25 A. Would I agree that bacteria is of greater relevance



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2 than particles? It depends. It depends if you mean  
3 bacteria that we know are there, or bacteria that we see;  
4 and particles that we know are sterile, or particles that we  
5 know may contain bacteria. We're talking about  
6 probabilities here, and so it depends.

7 BY MR. C. GORDON:

8 Q. I'm talking about particles that don't contain  
9 bacteria versus actual bacteria.

10 A. Well, to my understanding of it, bacteria do exist  
11 on their own in air, but generally it's -- bacterias are  
12 carried by a vector: droplets of water, droplets of  
13 moisture, droplets of blood, or skin cells or dust. And so  
14 if you can guarantee that particles are sterile, have no  
15 bacteria and have no harmful effects, then bacteria are more  
16 important than particles. But until you can guarantee that  
17 all particles in the air are sterile, I, as a surgeon, would  
18 not want airborne particles in my operative field. And so  
19 it's difficult to completely separate the two, to completely  
20 separate particles from bacteria, because the form that  
21 bacteria take in an operative -- in an operating room are  
22 stuck to particles.

23 Q. When you were sampling the bacteria in this  
24 experiment, were you only sampling free-floating bacteria or  
25 were you also sampling bacteria that were traveling on

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2 particles?

3 A. We would have sampled both.

4 (Reporter clarification.)

5 A. This would have sampled both.

6 MR. C. GORDON: Let's turn to 3615.

7 THE COURT REPORTER: Would it be possible to have  
8 a short break?

9 MR. C. GORDON: I am sorry. I apologize. We'll  
10 take a break.

11 THE VIDEOGRAPHER: This is the end of DVD 1 in  
12 volume 1 in the deposition of Dr. McGovern. We are going  
13 off the record at 11:28. The recording has stopped.  
14 (11:28 a.m.)

15 (Break taken.)

16 (11:42 a.m.)

17 THE VIDEOGRAPHER: Okay. This is the beginning of  
18 DVD 2 in volume 1 of the deposition of Dr. Paul McGovern.  
19 We're back on the record at 11:42.

20 BY MR. C. GORDON:

21 Q. Dr. McGovern, if I could direct you to page 3615  
22 through 3626.

23 A. Yes.

24 Q. Is this another draft of the same study we've been  
25 talking about this morning?

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2 A. It is indeed, yes, another draft of this study that  
3 we've been talking about.

4 Q. And does the fact that this one has a list of  
5 names -- author names on it, suggest where it comes in the  
6 sequence of drafts?

7 A. It is likely to be after the first document we've  
8 discussed, but I do not know if this is before or after the  
9 second document that we've discussed. I can't tell.

10 Q. If you turn to page 3626, there are a couple of  
11 notes highlighted in yellow. One notes:

12 "Haven't re-done the references yet, will do so.

13 "Results, I haven't swapped round experiment 2 and  
14 4."

15 A. Yes.

16 Q. Are those your notes?

17 A. I don't remember.

18 Q. You described a process whereby this the write-up  
19 of this experiment went through several versions with input  
20 from several different people; is that right?

21 A. Yes.

22 Q. Do you know who had input in addition to the people  
23 listed on 3615?

24 A. I am not aware that anyone else had any -- I don't  
25 recall anyone else having any input into the write-up.

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2 THE VIDEOGRAPHER: Can I pause you a second. Your  
3 mic has fallen off.

4 BY MR. C. GORDON:

5 Q. Was this paper ever finalized?

6 A. Define "finalized".

7 Q. Where everybody who was involved in its authorship  
8 said, "Yep, this is a final version. I'm good with this."

9 A. No, I don't think so. A finalized paper would be  
10 one which had been accepted and published in a peer-reviewed  
11 journal.

12 Q. Okay. Was this ever submitted to any journal for  
13 publication?

14 A. This experiment was submitted to a meeting as  
15 a presentation. I can't remember which meeting, but it was  
16 rejected -- I think it was the American Academy of  
17 Orthopedic Surgeons. I would have to check that, but that  
18 was the meeting it was submitted to. So it was submitted  
19 and rejected.

20 Q. And when you say it was submitted, you're talking  
21 about a one-page summary?

22 A. An abstract of this. The form for such  
23 presentations is that an abstract is submitted and the study  
24 is accepted or rejected, based on that abstract.

25 Q. Was it submitted to more than one? Was the

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2 abstract submitted to more than one group?

3 A. Not to my recollection.

4 Q. Was there any discussion about submitting the full  
5 paper, with the complete results and the analysis and the  
6 discussion, to a journal for publication?

7 A. Well, the process of writing up is with the  
8 intention of submitting it to a journal. But I think most  
9 clinicians would agree that the barrier of entry, or the --  
10 we would agree that it is harder to get something published  
11 in a journal than it is to have something presented at  
12 a meeting. And so all these documents that we've been  
13 discussing were working towards the intention of having it  
14 published in a journal. But having been peer reviewed by  
15 the review process, the abstract being reviewed and  
16 rejected, at that point it wasn't taken further.

17 Q. Who made the decision not to pursue this any  
18 further by trying to submit it to a publication, or submit  
19 the abstract to other organizations?

20 A. I don't remember.

21 Q. At what point did you first meet Mark Albrecht?

22 A. I don't remember.

23 Q. Do you recall the circumstances under which you  
24 first met him?

25 A. It would have been in the U.K. and it's likely that

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2 it was -- well, in the Newcastle area. It would have been  
3 in relation to a subsequent experiment looking at airflows  
4 in operating rooms, operating theaters.

5 Q. Was Professor Edwards-Jones involved in any  
6 discussions about whether to try to submit this to any  
7 publication?

8 A. I don't remember if professor Edwards-Jones was  
9 involved in discussions about submission, or which  
10 publications or meetings would be targeted for submission.  
11 I remember the discussions with Professor Edwards-Jones were  
12 regarding the microbiology and plates, things of that  
13 regard, but I don't remember if discussions with  
14 Professor Edwards-Jones involved a submission.

15 Q. I want to be sure I understand. Your testimony is  
16 that because one conference group rejected a one-page  
17 summary for a presentation to that conference, you decided:  
18 that's it. We're not going to do anything further with this  
19 research?

20 MR. SACCHET: Object to form.

21 A. I think that is part of the reason that this wasn't  
22 pursued further. I think that in this case the experiment  
23 is poorly designed, and because the -- because presenting  
24 something in a meeting is generally easier than getting  
25 something published, it seemed extremely unlikely, so as to

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2 be effectively impossible, that this study would be accepted  
3 for publication, to my recollection.

4 BY MR. C. GORDON:

5 Q. In connection with some of your subsequent studies  
6 of Bair Hugger, your initial attempts to get them published  
7 were rejected by multiple journals; right?

8 A. Correct.

9 Q. And you kept trying them until you found a journal  
10 that was willing to publish them?

11 A. Correct.

12 Q. Why the difference?

13 A. The difference being that when you do an experiment  
14 and get it -- try to get it published, you have to go  
15 through a peer-review process, entirely appropriately. It  
16 is known that experiments with negative findings, or with no  
17 findings, generally are accepted less frequently than those  
18 with positive findings. Furthermore, this is the first  
19 experimental study that I'd ever done in clinical practice.  
20 I'd done audits, but I had not been closely involved with  
21 designing an experiment of this nature before. And it  
22 became clear to me, and I believe my co-authors, that the  
23 design of the experiment was really not representative of  
24 surgical practice.

25 And so, to summarize, the reason that this paper

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2 was not pursued, and the others were, is that the other  
3 papers were good papers and good studies, and this  
4 wasn't a good study.

5 Q. Tell me why this was not a good study.

6 A. This study did not take into account any  
7 statistical significance of any data. The way it was  
8 designed was we had an idea and put some bacterial plates  
9 out, and I had a particle counter and learnt how to use it,  
10 and thought: I'll look and see if I can see anything. And  
11 really, a study of this nature requires planning with  
12 a statistician to work out what potential results may be,  
13 and how one may produce a statistically significant result.

14 Also, I think that it would have been worth doing  
15 some preliminary studies in real life to get a baseline.  
16 What I mean by that is putting some bacterial plates in  
17 a real operation in the corner of an operating room to  
18 see whether there was a difference between a real  
19 operation and whether -- sorry, bacterial settle rates  
20 in a real operation, or a set-up which was closer to a  
21 real operation, so a simulated set-up which was closer  
22 to a real operation when compared with this design,  
23 which really didn't have many people in the room, did  
24 not set the patient up in a way which was representative  
25 of an operation which we'd be interested in looking at.



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2 It looked for bacteria in an environment which is  
3 designed to minimize bacterial load in the air. And  
4 it's not really surprising that there were very few  
5 bacteria.

6 But all this together means that a peer reviewer  
7 would, in all likelihood, look at this study, see that  
8 it was a very flawed design, and conclude that it wasn't  
9 worth publishing.

10 Q. I'm sorry, I'm not understanding what you meant by  
11 "minimizing the bacterial load in the air."

12 A. So, a laminar flow operating room, the purpose  
13 of it is to -- or one of the purposes of it -- is to clear  
14 bacteria, or potentially bacterial-laden particles away from  
15 the operative field. That is one of the reasons for having  
16 a laminar flow operating room in the first place. And so,  
17 given that the operating room is a clean environment, if  
18 there are no, or very few, sources of potential particles  
19 which are the operating room staff, the procedure itself,  
20 the moisture thrown up from the procedure, the patient, the  
21 equipment used by the patient, then it's not surprising that  
22 there were any particles there. It is not representative of  
23 real life.

24 (Reporter clarification)

25 A. To continue the theme, if I put bacterial settle

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2 plates down in an operating room I'd expect to find zero  
3 bacteria, and the experiment that we set up, given my  
4 inexperience at the time, was one which I thought would be  
5 representative of an operating environment, but really  
6 wasn't. It was more representative of an empty operating  
7 room because of the controls that were put in place by  
8 limiting the number of people in the operating room, keeping  
9 people outside the laminar flow boundary and minimizing  
10 movement and any sources of air disruption in the operating  
11 room.

12 Q. Do you recall having any discussions with  
13 Professor Edwards-Jones about the likelihood of finding  
14 bacteria under these circumstances?

15 A. I don't remember.

16 Q. Do you recall any discussions, after this was done,  
17 about "Maybe we should try it again and do it a different  
18 way to make it more realistic in terms of what a real  
19 operation would be"?

20 A. I don't remember. I -- the reason that we -- I  
21 mentioned previously putting bacterial collection plates in  
22 a real operation, but there are ethical issues with that,  
23 understandably, because doing any research in the vicinity  
24 of a patient is one which rightly needs a lot of oversight,  
25 and to -- it would be unrealistic to do that, and probably

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2 not permissible to put bacterial plates in a real operating  
3 room to collect -- to sample bacteria without full ethical  
4 approval, which is a different -- would be a completely  
5 different experiment. So it wasn't something which we could  
6 just try and see if we saw anything.

7 Q. Okay. Going back to your discussion about the  
8 statistical analysis, what data would you have, in  
9 hindsight, wanted to subject to some sort of statistical  
10 analysis?

11 A. What I would have done is designed the experiment  
12 with a statistician, or with someone who had much more  
13 experience of statistics than I, to establish what numbers  
14 we might be expecting and what statistical tests, if any,  
15 would be appropriate. Now, in an area in which we have very  
16 little experience, such as this, a scoping experiment might  
17 be appropriate to simply use the equipment and see what you  
18 see, as I've said before, to get an idea for whether there  
19 were any particles in the air, whether there were any  
20 bacteria, because if you have zero bacteria, you can't do  
21 a statistical analysis. If you have one or two, it might  
22 require a different statistical test. If you have  
23 thousands, it might require a yet different statistical  
24 test, which influences the study design. My expertise would  
25 be in relating something to surgical practice, but my

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2 expertise would not be in designing a study to make it  
3 statistically significant. So that's why I would  
4 collaborate with someone who had expertise in that area, in  
5 the future, were I going back over this research, to make  
6 the data as valid as possible and as useful as possible.

7 Q. Okay. I guess I'm having trouble understanding  
8 what kind of statistical analysis you'd do if you're looking  
9 to see if something causes an increase, and all you get are  
10 zeros.

11 MR. SACCHET: Object to form.

12 BY MR. C. GORDON:

13 Q. What is the statistical issue there?

14 MR. SACCHET: Object to form.

15 A. Statistical issue with what?

16 BY MR. C. GORDON:

17 Q. Well, for example, when you blew the air from  
18 a Bair Hugger onto a settle plate, you got zero bugs?

19 A. Correct.

20 Q. What is -- what statistical analysis could be done  
21 there?

22 MR. SACCHET: Object to form.

23 A. In that experiment, where you simply blow something  
24 over a settle plate, none. There is no statistical test,  
25 which is why perhaps an experiment may involve -- and this

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2 why I would collaborate with a statistician -- were I to  
3 look in detail at bacteria particles from a Bair Hugger  
4 unit, I would maybe use multiple units, adjust the  
5 conditions they were in. This experiment was not conceived  
6 to look at the outflow ports of Bair Huggers.

7 Really, I mentioned earlier a scoping  
8 exercise. In retrospect, this was a scoping exercise  
9 which I hoped would be publishable; but in doing this  
10 scoping exercise I learned a little about how  
11 experiments are conducted, how not to conduct  
12 experiments, and what -- how to approach designing  
13 a scientific study so that the data are valid and so it  
14 is publishable in some context. The outflow of the  
15 Bair Hugger, those data would not have been publishable  
16 because they are an aside. They are something that we  
17 did because we had some settle plates, and we had a  
18 Bair Hugger. And so we were looking to see if we could  
19 see anything. It was an informal look, a glance, at  
20 a scoping exercise to see if we could find anything  
21 interesting.

22 BY MR. C. GORDON:

23 Q. Let's see if we can summarize what you learned in  
24 doing this as to how not to do it, or what's the right way  
25 to do an experiment. One of the things you mentioned was

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2 that there were fewer personnel than would ordinarily be  
3 present in a surgery; is that right?

4 A. Yes.

5 Q. So for further research, you'd want to have the  
6 normal number of personnel; right?

7 A. Ideally, this -- what would be done would be  
8 collecting bacterial samples in real operating -- in  
9 hundreds, probably, of real operations, and using -- gaining  
10 a large amount of data, strategically gaining that data to  
11 establish what was a necessary amount of data to be able to  
12 statistically analyze. So yeah, you would -- you might  
13 particle count, you may bacteria count. You may use active  
14 sampling, passive sampling, and ideally it would be in  
15 a real operating environment. The design of the particle  
16 counters would have to be different from the one that was  
17 used because it was quite bulky. It would have got in the  
18 way of the operation. It would be very difficult to  
19 accurately sample bacteria.

20 You would also take a bacterial swabs from the  
21 wound, and you would randomize patients to being warmed  
22 with a Bair Hugger or not. You may have different arms  
23 of the study. You would need to control for patient's  
24 age, the operation they were having, the length of the  
25 procedure, the patient's temperature. It would be

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2 a huge and very complex study, and one which, without  
3 a very, very large amount of funding, would be  
4 unfeasible.

5 Q. Do you recall any discussions with anyone about  
6 trying to accomplish a study along the lines you've just  
7 described?

8 A. I've had frequent discussions with Mike Reed, but  
9 not in terms of actually trying to plan a study, but in  
10 terms of mentioning that that would be desirable. That  
11 would -- a well designed, multicenter, randomized control  
12 study would provide more robust information which would be  
13 valuable.

14 Q. So at what point after you had done this study did  
15 you decide to do further research on the Bair Hugger?

16 A. In terms of time, I don't remember. It was  
17 sometime after the experiment was conducted. This, as you  
18 can see, went through multiple revisions. So I spent some  
19 effort trying to get this up to standard. But the process  
20 of a junior doctor writing their first paper is a torturous  
21 one, and a long one, as can be seen by the many slightly  
22 varying revisions that I've produced. I don't remember when  
23 the next study started. I don't remember if writing up of  
24 this continued after, during or before the subsequent  
25 investigations took place.

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2 I had the particle counter and I was continuing to  
3 try to learn how to use it. I would informally sample  
4 air in operating rooms at home to see what type of  
5 scenarios produced what type of results with it, to try  
6 and learn how to use it better. But I don't remember  
7 the exact timescales of those.

8 Q. What was the next Bair Hugger related research  
9 activity you undertook?

10 A. I think it was the study in which we used the --  
11 well, the next experiment that I was involved in. So I was  
12 involved in writing up several papers and involved in the  
13 writing phase of those, but the next experiment that I was  
14 involved in was, to the best of my recollection, one in  
15 which we used a bubble generator to visualize airflow in the  
16 presenting room, in an experimental set-up.

17 Q. Whose idea was that?

18 A. Whose idea was?

19 Q. To use a bubble generator to visualize airflow?

20 A. I don't remember.

21 Q. Was it yours?

22 A. It was not mine.

23 Q. Was it somebody connected with Augustine?

24 A. I don't --

25 MR. SACCHET: Objection to form.



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2 BY MR. C. GORDON:

3 Q. Was Mark Albrecht involved in this bubble  
4 visualization?

5 A. Yes.

6 Q. How was he involved?

7 A. Mark Albrecht was involved, was in the UK for the  
8 experiment, for collection of some of the data, and helped  
9 to design the experiment, helped conduct the data  
10 collection, helped -- well, he was the person who knew how  
11 to use the bubble generator. And so he used that, directed  
12 its use, and was involved in statistical analysis and  
13 writing up.

14 Q. What was your role in that?

15 A. My role was to help design the theater layout, the  
16 operating room layout, and to advise on patient positioning,  
17 on surgeon positioning, anesthesia screen positioning,  
18 anesthesiologist positioning, and to advise on how an  
19 operation was set-up in real life, in an effort to best  
20 simulate a situation which was as realistic as possible.

21 Q. Do you know Robin Humble?

22 A. I do.

23 Q. When did you first meet him?

24 A. I don't remember. I don't remember if it was  
25 before this bacterial particle sampling experiment we've

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2 been discussing. I don't remember if it was before that or  
3 after that.

4 Q. In what context did you meet him?

5 A. I don't remember when I met him. I don't remember  
6 the context I met Robin Humble in.

7 Q. Whenever you first met him, what was your  
8 understanding of who he was?

9 A. My understanding now is that he is -- he works with  
10 HotDog, the company HotDog, to distribute it in the U.K. I  
11 don't remember what my understanding of his role was at that  
12 time.

13 Q. Did you meet him in a professional context or a  
14 social context?

15 A. I remember working -- I remember him being present  
16 during the experiments with the -- or some of the  
17 experiments at Wansbeck Hospital using the bubble generator.  
18 I don't remember if I have met him before in another  
19 context.

20 Q. Did he have anything to do with the actual running  
21 of the experiment, the microbiology one that we've been --

22 A. Not to my recollection.

23 Q. Did you meet him before or after you met Albrecht?

24 A. I don't remember. It may have been around the same  
25 time, but I don't remember if I met him before or after Mark

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2 Albrecht. I don't remember who was at Wansbeck Hospital  
3 first. I don't remember if I met one of them and another  
4 one came on a different day. I don't remember if it was in  
5 the same day, a couple of days, weekends. I don't remember  
6 meeting Robin Humble. I remember him being at Wansbeck  
7 Hospital.

8 Q. In the first bubble experiment you did, you  
9 actually compared Bair Hugger to HotDog, right?

10 A. I believe so, yes.

11 Q. Had Wansbeck Hospital acquired a HotDog unit prior  
12 to that?

13 A. I don't remember. I remember that Wansbeck  
14 Hospital did look at and eventually transfer over to HotDog  
15 as their warming solution of choice. I don't remember if  
16 that process had occurred, or if it had started at the time  
17 of the bubble experiment. I think it had not happened.  
18 I don't think Wansbeck was running HotDogs as part of their  
19 general practice at the time of that experiment, but I can't  
20 remember the exact dates.

21 Q. Do you know how it came to be that Wansbeck had  
22 a HotDog unit to even use when you did that bubble -- that  
23 first bubble experiment?

24 A. I don't.

25 Q. Did you have any input into the initial decision to

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2 do the bubble experiment?

3 A. I was working on the -- this project, and it  
4 seemed -- as I'd been working with Mike Reed in the area,  
5 I was a junior doctor under him, and I worked -- he asked me  
6 if I wanted to be involved in more research in it. I  
7 haven't -- my aim was to get a paper published. That's  
8 the -- that was the prime reason to get involved in the very  
9 first place, was because I wanted to get a paper, or more  
10 than one paper, published, which is why I went through so  
11 many iterations of this, because I did want to publish  
12 something. I was offered to be involved with more studies,  
13 and so I agreed.

14 Q. Going back to the microbiology study, given your  
15 eagerness to publish a paper and all the effort you put into  
16 the various versions of it, why didn't you just try  
17 submitting it somewhere?

18 A. A couple of reasons. First, it seemed futile.  
19 Second, I haven't finished every piece of audit or research  
20 work that I've started. I've got quite a lot of things  
21 which fall by the wayside. It's not uncommon for me, and  
22 I think many of my colleagues, to start something and  
23 realize that you're barking up the wrong tree or going down  
24 a dead end. And so this is one of several efforts. I've  
25 had other audits and other -- no research in this field, but

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2 in other areas which I've started, and then realized that it  
3 wasn't going to achieve anything, and then not continued  
4 with it.

5 Q. Had you published anything prior to the time you  
6 did the microbiology study?

7 A. I had been a very junior author on one paper which  
8 looked at the development of electronic software in a trauma  
9 unit. That was in 2007, and my involvement in that was  
10 performing an audit on, I think, surgeons' perceptions of  
11 how trauma meetings are performed in the morning meeting in  
12 a surgical unit that I worked in in UCLH, when I was  
13 a second-year doctor. And so this is the first experiment  
14 which I was more closely involved with in the design of.  
15 I had not done any research or anything in this area, and  
16 tried to design anything before. I had one publication but  
17 was a very junior author and did a very small part of the  
18 larger projects.

19 Q. Did there come a point in time with the  
20 microbiology study, when you'd gone through various drafts  
21 and put all this effort in, that somebody put their hand on  
22 your shoulder and said, "Mark, give this one up. Move on to  
23 something else."

24 A. Mark?

25 Q. I'm sorry. "Paul".

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2 A. No. At no point did anyone say "This is a" -- you  
3 know, "Give this up." I -- as a more senior trainee,  
4 Ms. Srinivas was not involved initially, but helped me quite  
5 a lot with trying to get this up to a standard which we  
6 thought might be publishable. But really, this was not  
7 a situation of anyone discouraging me; this was a situation  
8 of me realizing that it wasn't going to get published,  
9 particularly after it had been rejected for a scientific  
10 meeting. And going through all the iterations, seeing that  
11 there was very little substance which a reviewer would grab  
12 on to and think: this is worth publishing.

13 And I think that -- I still have that opinion.  
14 Having been involved with the review process more, as  
15 I've got more senior, if this were presented to me as  
16 a reviewer, I'd reject it. It doesn't -- it's -- I'd  
17 try and, if I were reviewing it, offer some helpful  
18 advice and say that "You need to be a bit more focused  
19 as to what you're trying to show and have an idea of how  
20 you're going to show it," but in this form, and any  
21 forms that we got to, it is not something that would be  
22 in a peer-reviewed journal that would be of sufficient  
23 note to be worth my career.

24 You can get something published in some  
25 journals, but if they're not listed on PubMed, if

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2 they're not of a certain standard, then they're not  
3 declarable as a trainee, they don't count towards your  
4 professional development as a trainee, and they're not,  
5 therefore, a line on your CV which is worth putting,  
6 which is worth including. And so, if I'm to publish  
7 something, I want it to be published in a respected  
8 peer-reviewed journal, not one of these journals that  
9 takes a fee and publishes anything. And I came to the  
10 conclusion that this was only publishable in one of  
11 those journals and therefore not worth pursuing any  
12 more.

13 Q. Before luncheon, I'll take what should be a pretty  
14 quick topic.

15 If you turn to page 3671.

16 A. Yes.

17 Q. When you were sharing with us your background and  
18 you talked about your experience at Medway, I thought  
19 I heard you say that you had been involved in an audit of  
20 Bair Hugger versus HotDog, or something involving the --  
21 that Medway was looking at Bair Hugger, HotDog, and some  
22 other warming modality?

23 A. I didn't say I'd been involved in an audit like  
24 that.

25 Q. Okay, then I misspoke. What does page 3671 refer

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2 to?

3 A. This was -- let me see.

4 Q. I guess it goes on to 3673.

5 A. Yeah. This was a proposal for an audit in which  
6 the -- an audit into whether different warming technologies  
7 altered ambient temperatures in operating rooms.

8 Q. What were the different technologies?

9 A. I believe -- yeah, HotDog and Bair Hugger.

10 Q. What's the difference between an audit and -- well,  
11 strike that. What's an audit?

12 A. So, an audit is -- I mean, it seemed like you were  
13 starting to ask what the difference between audit and  
14 research is, and it's probably worth discussing the  
15 difference in terms of each other. An audit is where you  
16 collect data and you examine it against a standard, and  
17 research is where you -- generally where you make a change  
18 to practice and monitor that change. An audit, therefore,  
19 is collecting data but not changing practice at all. And  
20 research generally changes something.

21 Now, this is particularly relevant for  
22 anything involving patients, because with an audit, you  
23 don't make any change to a patient's care or anything  
24 about the environment of a patient that you weren't  
25 already doing. You are looking at what is done. With



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2 the research, you change something and look at the  
3 impact that change has.

4 A big difference between them is the ethical  
5 considerations of the two, because if you're changing  
6 something with relation to patients, there comes into  
7 play a potential conflict of interest if I were to --  
8 if anyone, a clinician, were to change any aspect of  
9 patient care, there is a potential to change care to  
10 the detriment of the patient. And that being the case,  
11 any research needs to be examined by an ethics  
12 committee. Audit does not need to be examined by an  
13 ethics committee because it does not change the patient  
14 experience, or change anything that happens to  
15 patients.

16 So in this case, this is an audit, because  
17 temperatures are taken in theaters for general  
18 monitoring anyway. Ambient temperatures are monitored  
19 because there is a temperature sensor on the wall. And  
20 so it really, from my recollection -- I haven't read  
21 this in detail for a while, but from my recollection --  
22 it was asking staff to note down the temperature in the  
23 operating room and which warming technology was used.  
24 It did not attempt to alter the warming technology  
25 which was used. Medway happened, through no -- through

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2 circumstance, to be using both HotDogs and Bair Huggers  
3 at the time I was working there.

4 Q. When you first started there, were they using both?

5 A. I don't remember if they started using both  
6 when I -- if they were using both when I started there.

7 Q. Did you have any input into the decision on  
8 Medway's part to give HotDog a try?

9 A. No.

10 Q. Do you recall having any communications with anyone  
11 connected with Augustine, suggesting that they provide them  
12 with some cost benefit analysis as a way of persuading them  
13 that they should try HotDog?

14 A. I may have -- I don't remember if I'd -- have ever  
15 asked about cost benefit analysis with regard to Medway.  
16 I have asked about costs of Bair Huggers and HotDogs and  
17 other technologies -- well, anywhere I've worked, which has  
18 looked at both. So it was something I was interested in.  
19 So I may have asked what prices Medway was paying. I may  
20 have ask the theater staff what prices they were paying for  
21 HotDogs, for Bair Huggers, because I generally am interested  
22 in how much things cost, anyway. I'd ask how much  
23 orthopedic implants cost, or how much an operation costs.  
24 It is just something that interests me. So it is quite  
25 possible that I'd have asked about the cost of Bair Huggers

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2 and HotDogs, although I don't remember a specific incident  
3 of doing so.

4 Q. Well, to be more specific, you don't recall  
5 communicating with Robin Humble and suggesting that he  
6 provide Medway with a cost benefit analysis?

7 A. I was in contact with Robin Humble when I was at  
8 Medway, but -- I don't remember any communication to that  
9 effect, but it's possible. I don't remember.

10 Q. Okay. What happened with the -- your audit  
11 proposal you see on 3671?

12 A. I don't think this was the only audit that I did or  
13 tried to do in Medway. I don't recall outputting anything  
14 with regards to patient warming when I was at Medway.  
15 I think I tried to -- there was this audit, and there was  
16 another one in which different theaters were trialing  
17 HotDog, and they were alternating between Hotdogs and  
18 Bair Huggers; and I thought that would be an opportunity for  
19 an audit, because I had not instigated use in different  
20 theaters or anything, and I thought this was an opportunity  
21 to sample, I think, temperatures, maybe particles, but I had  
22 some ideas, but nothing got produced. Nothing became of any  
23 of these ideas, as far as I remember.

24 Q. So no audits were actually performed?

25 A. Data may have been collected but nothing was

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2 completed. Because there's this audit form. I -- you know,  
3 this 3673. I do not remember if this sheet moved out of  
4 draft stage and was put in any operating rooms, and if any  
5 that was collected. I don't remember if I picked any sheets  
6 up or did anything with any of the data. But this did  
7 not -- whatever stage it got to, it did not get to a stage  
8 of me having written anything for presentation, as far as  
9 I remember.

10 (Reporter clarification.)

11 Q. So you don't remember even compiling any  
12 comparative data?

13 A. I -- I don't remember if I did. I remember having  
14 meetings with senior nursing staff to try to set this up,  
15 and I remember that some seniors were interested in it.  
16 They thought this was something worth pursuing, and some  
17 weren't interested. And so I remember a lot of meetings  
18 about whether this could go ahead, because in this sort of  
19 audit you need buy-in from all staff, because they can't be  
20 distracted from their core job. This is something that they  
21 would only do if they had a moment to do it, and that  
22 requires all staff to be aware of it, and that requires  
23 senior staff to be happy that you're alerting more junior  
24 staff to it, and for them to be on board, and to be  
25 cooperating.

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2 I don't -- I remember a lot of meetings with more  
3 senior surgical theater staff about whether this could  
4 go ahead, but I don't remember where we got to in this  
5 audit, or in this proposed audit. I don't remember at  
6 what stage, if any, data was collected at all, or if  
7 some data was collected, or if I compiled any data or  
8 anything. I've got lots of -- well, as I say, there's  
9 been lots of audits that I -- obviously I've started in  
10 the past, which I've then realized, for practical  
11 reasons or logistical reasons, have not gone anywhere.  
12 And I don't remember if this is one of those that got  
13 nearly done and fell at the last hurdle, or didn't get  
14 past this stage.

15 Q. And so, as you sit here today, you don't remember  
16 that there -- whatever you did, did or did not show any  
17 difference between HotDog and the Bair Hugger?

18 MR. SACCHET: Objection to form.

19 A. I did -- nothing that I did at Medway showed  
20 anything interesting. Whatever stage I got to, there was no  
21 point at which I found an interesting -- whether or not --  
22 I mean, it wouldn't have been statistically significant  
23 because it was not researched, but whether I found anything  
24 which was noteworthy either way. Because if I had found  
25 something noteworthy either way, then I would have taken it

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2 forward. But yeah, as I sit here today, there's nothing  
3 I recall which was worth -- which is worth mentioning.

4 BY MR. C. GORDON:

5 Q. And when you say, you know, something worth  
6 mentioning, that would be if there was a difference?

7 A. Or if there wasn't. If -- you see, this is -- the  
8 problem with this audit, looking at it now, with  
9 a reviewer's mind, my question to my more junior, less  
10 experienced self, is: what's the point? What's the point of  
11 looking at whether temperatures go up and down in  
12 a small-scale thing? Temperatures fluctuate quite a lot in  
13 operating rooms, and it is a constant complaint of surgeons  
14 and circulating staff that it is either too hot or too cold,  
15 and there are lots of things that can confound the  
16 temperature in the operating room.

17 And again, it is a sort of speculative thing. If  
18 you see that temperatures are on average 5 degrees or  
19 10 degrees higher when using one technology or another,  
20 that may be of interest. And if you don't find  
21 anything, then it's almost what you would expect. But  
22 again, in this sort of thing, I'm motivated partly by  
23 the fact that I am encouraged to have audits produced,  
24 and I am encouraged to have presented audits locally.  
25 And so there is a certain amount of looking for things

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2 that I can audit as a training surgeon, and there is  
3 a -- yeah, you're looking for things that might be  
4 interesting to report on. But I -- as I say, I don't  
5 remember if anything noteworthy came of this, and  
6 I don't remember what stage it got to.

7 MR. C. GORDON: That's a good spot to take  
8 a break, or a lunch hour.

9 THE VIDEOGRAPHER: Going off the record at 12:33.  
10 (12:33 a.m.)

11 (Break taken.)

12 (1:40 p.m.)

13 THE VIDEOGRAPHER: We're back on the record at 20  
14 to 2. The deposition has been joined by ...

15 MR. SHACKLADY: Bryan Shacklady. I am English  
16 solicitor from Forsters LLP, representing Mr. McGovern.

17 THE VIDEOGRAPHER: Okay, which means that Andrew  
18 Head has left for the time being. On the record at 1:41,  
19 counsel.

20 BY MR. C. GORDON:

21 Q. Dr. McGovern, have you talked to Mike Reed since he  
22 had his deposition taken?

23 A. When did he have his deposition taken?

24 Q. In December.

25 A. Not to my recollection, no.

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2 Q. Okay. You know who Scott Augustine is; correct?

3 A. I do.

4 Q. When is the last time you spoke with Scott  
5 Augustine?

6 A. A few months ago. It was some time in 2016. I'd  
7 say four to six months ago, but it's a bit of a guess.

8 Q. There are some e-mails with him. We'll get to  
9 them, and we can talk about that. But I take it, then, you  
10 have not spoken with him about your deposition?

11 A. No, that's correct. I have not spoken with Scott  
12 Augustine about this deposition.

13 Q. Have you spoken with Mark Albrecht at all about  
14 this deposition?

15 A. No, I've not. I haven't spoken to Mark Albrecht  
16 for -- I don't think I've spoken to Mark Albrecht since this  
17 whole process started, so no.

18 Q. By "this whole process", what do you mean?

19 A. Since -- certainly in the last year, I don't recall  
20 speaking to Mark Albrecht.

21 Q. Okay. Have you had any communication with  
22 Mr. Albrecht via e-mail in the past year?

23 A. In the past ... I don't think I have, in the past  
24 year. I don't remember the last time I spoke to Mark  
25 Albrecht. It may have been a year or more ago. I think it



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2 was -- he asked me to do reference for him, it could be  
3 a year, two years ago, and we've had some communication, but  
4 I can't remember the dates when I last spoke to him. Not  
5 recently. I haven't spoken to Mark Albrecht recently.

6 Q. Okay. I'd like to direct your attention to  
7 exhibit 1A, page 350. Is that an exchange of e-mails  
8 between you and Mike Reed?

9 A. It is.

10 Q. In the top e-mail he -- apparently Mike -- is  
11 writing to you. He refers to the "Need to get the Wansbeck  
12 bubble experiment written up ASAP"?

13 A. Yes.

14 Q. What is the Wansbeck bubble experiment?

15 A. That is the -- to my recollection, the second  
16 experiment we were speaking about earlier, in which the  
17 bubble generator was used in an operating room in an  
18 experimental set-up to better understand the flow of air in  
19 the operating room. That was a study which Mark Albrecht  
20 was involved with.

21 Q. Okay. And as of July 18, 2010, had that bubble  
22 experiment already been done?

23 A. I believe so, just by the content of the e-mail.  
24 I don't remember when the bubble experiment was completed,  
25 but given that Mike Reed, in that e-mail, is speaking in the

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2 past tense, or referring to it as though it were in the  
3 past, it would seem that that experiment had finished at  
4 that point.

5 Q. Your response to him was: "The one we did with all  
6 the video? I thought mark was writing that one up." Is  
7 that right?

8 A. Yes, yes.

9 Q. "Mark" refers to Mark Albrecht?

10 A. That's right.

11 Q. You thought he was going to be doing the principal  
12 authorship of the bubble study?

13 A. Well, part of it. Different parts of the paper are  
14 written by different individuals. And so we all had  
15 different sections of the paper to complete. Mark Albrecht  
16 specifically dealt with the statistical results section. I  
17 was more involved with the preamble, the introduction, and  
18 the methods. But in terms of the exact delineation of work,  
19 I don't remember what proportion of was which, but I was  
20 involved in writing some sections more, and some sections  
21 Mark was involved with writing more.

22 Q. Who was primarily involved with writing the section  
23 of that paper that compared the infection rates from the  
24 Bair Hugger period to the HotDog period?

25 A. That was part of the paper which I was not really

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2 particularly involved with. The infection rates were part  
3 of data that Mike Reed had, and I did not really have much  
4 to do with that data. I didn't process it, or I knew it was  
5 there, and it was probably included in some e-mails --  
6 including it -- but I didn't process that data or have much  
7 to do with that section of the experiment. My main  
8 involvement with that study in that paper was the  
9 experimental phase in the operating room.

10 Q. Going further on this e-mail on page 350, you said:

11 "Have sent a couple more versions of the original  
12 one we did with Val, can resend the latest this evening  
13 when I get home if you want."

14 What does that refer to?

15 A. That refers to the first experiment we were  
16 speaking about earlier, which was the one with bacterial  
17 sampling with settle plates and the bacterial sampling  
18 device.

19 Q. So does this indicate that even after you had done  
20 the first bubble study, you were still working on trying to  
21 finalize the bacteria study?

22 A. It does.

23 Q. Okay. In fact you go on to say:

24 "Am keen to push that through as well as all the  
25 other stuff asap."

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2 A. Yes.

3 Q. And that refers to the bacteria. So as of  
4 July 2010, you were still keen to work on and get the  
5 bacteria study published?

6 A. Yes.

7 Q. Okay. The next paragraph you said:

8 "I think Augustine will help me to present  
9 this stuff round and about, am going to do a big  
10 submission run to various conferences to spread the  
11 word."

12 A. Yes.

13 Q. What was that a reference to?

14 A. That was a reference to attending a meeting in,  
15 I think, Copenhagen. There are many orthopedic meetings  
16 around the country and around the world, and they have  
17 associated fees with regards traveling to them, and joining  
18 fees and such. And my understanding was that Augustine's  
19 company would help me with those fees to present papers,  
20 were they accepted by the peer-review process.

21 Q. And when you talk about Augustine helping you to  
22 present "this stuff", does "this stuff" refer to the  
23 bubbles, the bacteria, or both?

24 A. It's not clear from that, and I don't remember what  
25 I meant at that time.

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2 Q. Okay. If you'd flip over to the other e-mail  
3 volume and turn to page 662.

4 A. Is this 2A?

5 Q. Yes.

6 A. 662?

7 Q. Yes. In the bottom, is that an e-mail from you to  
8 you?

9 A. At the bottom, er, yes.

10 Q. Is this kind of a way of keeping track of some  
11 notes?

12 A. Probably notes, yeah.

13 Q. Okay. And this is all in reference to that  
14 bacteria study; correct?

15 A. I don't know, because I haven't written what it's  
16 in reference to.

17 Q. Well, if you look further up, the couple of  
18 attachments are the "Particle and microbiology writeup draft  
19 3."

20 A. Where are we, sorry?

21 Q. Just on the Word document attachments. The  
22 attachments themselves aren't there, just to show.

23 A. Right, sure, yeah. "Particle and microbiology  
24 writeup draft 3", yes.

25 Q. Then if you look at page 663 also in this string,

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2 it's from you to Mike Reed: "This is the latest version  
3 (attached)."

4 A. Yes.

5 Q. "Having gone over it with" -- is it Shreya?

6 A. Shreya is Ms. Srinivas, the collaborator I  
7 mentioned earlier who wasn't involved in the experimental  
8 phase, but was helping with the write-up phase, the more  
9 senior trainee.

10 Q. And is there any doubt in your mind that these  
11 notes have something to do with that microbiology study?

12 A. No, these are related to the first study that we  
13 discussed earlier.

14 Q. Okay. There's one line that I -- in sort of the  
15 middle of your e-mail to yourself:

16 "In expert opinion of senior author (val)  
17 considered ideal simulation."

18 What does that mean?

19 A. I don't know.

20 Q. "Val" refers to Professor Valerie Edwards-Jones?

21 A. Valerie -- yeah, that's correct.

22 Q. And do you recall discussing with Professor Jones  
23 whether she thought the simulation that you conducted was an  
24 ideal simulation?

25 A. I don't remember what the discussion I had with

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2 Dr. Edwards-Jones in that regard was.

3 Professor Edwards-Jones's role was microbiological, rather  
4 than surgical, but I don't know what I'm referring to in  
5 that brief note.

6 Q. If you flip to page 735, a series of e-mails among  
7 you, Mr. Reed, and Val Edwards-Jones. In particular I want  
8 to draw your attention to one at the bottom where Val  
9 Edwards-Jones writes to you and Mr. Reed several things, but  
10 the one line in particular is:

11 "I want to put lots of settle plates down too  
12 so I will have the plan marked to place them in  
13 appropriate positions."

14 Do you see that?

15 A. Mm-hm, yeah.

16 Q. Were the settle plates placed pursuant to the  
17 determination of Professor Edwards-Jones as to what were the  
18 appropriate positions?

19 A. To the best of my recollection, it was discussed at  
20 the time. I don't remember if Professor Edwards-Jones  
21 insisted. I don't remember any disagreement. We all would  
22 have had an opinion on where the plates would go, and the  
23 reason for those choices would have been related to being  
24 inside and outside the laminar flow boundary, and practical  
25 position placements based on the experiment we were doing.

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2 But in terms of whether there was discussion or whether that  
3 was decided by Professor Edwards-Jones, I don't remember.

4 Q. If you'd turn to page 738, it looks like the top  
5 e-mail from you to Professor Edwards-Jones with a CC to  
6 Professor David Leaper and Mike Reed. A couple of phrases  
7 into this, you say:

8 "I'm surprised we got nothing from the plates  
9 set up next to the field. Even though the particle  
10 counter didn't pick [up] anything significant up here,  
11 I suppose it's possible that the table the micro  
12 sampling unit was on could block 'dirty' air flow from  
13 under the table. That might be clutching at straws  
14 though, particularly if plates placed under the table  
15 (where dirty air ought to land) didn't grow anything.

16 "I will have to think about any other  
17 potential errors in the design and discuss with  
18 Mr. Reed."

19 Did I read that correctly?

20 A. Yeah.

21 Q. Did you discuss any other potential errors in the  
22 design with Mr. Reed?

23 A. I had many discussions with Mr. Reed about the  
24 design of the experiment and the way that it was conducted,  
25 and the flaws and benefits of it. I don't remember



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2 a specific discussion, but I discussed this and other  
3 experiments frequently with Mr. Reed, as he was my  
4 supervisor.

5 (Reporter clarification.)

6 Q. Based on the timestamp, it looks like the e-mail  
7 that we've just -- that I just read from was in response to  
8 an e-mail from Mr. Reed to you and Professor Edwards-Jones  
9 and Professor Leaper, where Mr. Reed said:

10 "Isn't this surprising, and very valuable. I'm not  
11 sure whether it is reassured (I've been using them for  
12 years) or disappointed."

13 Did I read that correctly?

14 A. That's -- I read the same.

15 Q. What was your understanding, when you saw this, as  
16 to why Mr. Reed wasn't sure whether he should be reassured  
17 or disappointed?

18 MR. SACCHET: Object to form.

19 A. What was my understanding?

20 BY MR. C. GORDON:

21 Q. Yeah, when you read that, did you read that and  
22 just say "I haven't a clue what he's talking about," or did  
23 you have an idea what you thought he was referring to?

24 A. It was approximately seven years ago. I don't  
25 remember what I thought at the time.

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2 Q. Okay. Do you recall having any discussion with  
3 Mr. Reed as to what he thought was very valuable about the  
4 findings in this study?

5 A. I don't. If I did, I don't remember the content of  
6 such a discussion.

7 Q. If you turn to page 642, there's an e-mail from  
8 January 29, 2010, from Mr. Reed to you, and it looks like  
9 one other person, Sunit Patil?

10 A. Mm-hm, yes.

11 Q. Regarding a unique research opportunity?

12 A. Yes.

13 Q. And he refers to having a use of a thermal imaging  
14 camera from a Northumbria Fire Brigade. Are you aware of  
15 whether any experiments or demonstrations were done using  
16 a thermal imaging camera?

17 A. I recall this -- that discussions took place about  
18 a thermal imaging camera, but I was not present. I think  
19 I had another engagement and I was not available to partake  
20 in that "one night only" that is referred to in this e-mail.  
21 I wasn't around.

22 Q. Did you later hear that anything was ever done with  
23 the thermal imaging camera?

24 A. I can't remember. I can't remember what came of  
25 that.

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2 Q. Now when you initially wrote up the bubble study,  
3 was there, in the very first draft, a discussion comparing  
4 infection rates from the Bair Hugger period to the HotDog  
5 period?

6 A. I don't remember. I don't remember the content of  
7 different drafts, of draft 1 to however many drafts we had.

8 Q. When you initially conceived of the bubble study,  
9 from the very outset, did you plan to also do some sort of  
10 an observational retrospective comparison of infection  
11 rates?

12 A. No, not to my recollection.

13 Q. So, at some point after the initial conception of  
14 the bubble study, somebody came up with the idea of doing an  
15 observational look at the infection rates; is that right?

16 A. I don't know if the idea was floated after that,  
17 but my involvement was regarding the experimental phase. I  
18 don't know if it had always been planned, or if it was  
19 ongoing, or if it happened afterwards. But from my point of  
20 view, my initial involvement was with the experimental part  
21 of the study that involved setting up experimental  
22 operations and using the bubble counter; so not using  
23 infection data.

24 Q. At what point did you learn that infection data  
25 were being analyzed?

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2 A. I don't remember.

3 Q. Were you concerned about incorporating a discussion  
4 of infection rates into the paper on bubbles?

5 A. Not to my recollection.

6 Q. Could you turn to page 381. At the very bottom of  
7 the page there is an e-mail from you to Mark Albrecht with  
8 a blind carbon copy to Mike Reed; do you see that?

9 A. Yes.

10 Q. You say:

11 "Hi Mark.

12 "Looks good so far. Could you send as a word  
13 document so I can track some changes? In terms of flow  
14 I think it's good. My main concern at the moment is  
15 the statement about dropping of infection rates while  
16 using CFW, I think if we go into that we need more data  
17 and an in-depth discussion. I acknowledge the  
18 disclaimer about there being no evidence of  
19 a relationship, but it is contentious. It may be too  
20 easy for a reader/reviewer to pick holes in."

21 Did I read that correctly?

22 A. Yes.

23 Q. What was your -- so, what was your concern about  
24 the statement about the dropping of infection rates?

25 A. I recognized at the time that -- or even if there

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2 was an observation of a reduction in infection rates, that  
3 was not the same as proving causation. And we made very  
4 clear, I think, in the final paper, that this was not  
5 evidence of causation; it was a correlation. And this  
6 seems, to me, to be part of a conversation in which we  
7 ensure that the paper does not claim any more than it is  
8 able to do, which is that we observed a correlation but that  
9 doesn't prove causation in a drop in infection rates.

10 Q. Why did you believe it might be contentious?

11 A. Well, it's contentious if you claim something you  
12 cannot back up. So we -- if it appeared that we had claimed  
13 causation, that would not be correct unless we could prove  
14 causation. And so anything which -- any claim or statement  
15 made without adequate supporting evidence would be  
16 contentious if not correctly phrased, and with the  
17 appropriate qualifications as necessary being applied. And  
18 so that's what I meant by being contentious.

19 Q. And at this point, your thought was: let's just  
20 leave it out?

21 MR. SACCHET: Object to form.

22 A. I don't know what my thought at that time was.  
23 I couldn't say that that was my thought at the time.

24 (Reporter clarification.)

25 BY MR. C. GORDON:

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2 Q. In any event, Mark Albrecht's response was to  
3 basically say, "Let's -- we'll just leave it in, and see if  
4 the reviewers call us on it." Right?

5 MR. SACCHET: Object to form.

6 A. I don't remember that. Oh, was that here?

7 BY MR. C. GORDON:

8 Q. Yeah, page 382, an e-mail where he says:

9 "The whole review process is really  
10 a negotiation; if they are uncomfortable with what we  
11 have, they typically ask one to remove it and will not  
12 summarily dismiss the article. I'd suggest we try to  
13 include the infection data and only remove it should  
14 they require that."

15 Accurate?

16 A. That's what's written there.

17 Q. Is it your recollection that Mark Albrecht was the  
18 primary moving force to include infection data?

19 MR. SACCHET: Object to form.

20 A. I don't recall if that was the case.

21 BY MR. C. GORDON:

22 Q. You weren't only the one who had some concerns  
23 about including infection data --

24 MR. SACCHET: Object to form.

25 BY MR. C. GORDON:

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2 Q. -- were you?

3 A. I don't remember.

4 Q. Okay, turn to page 379. In the middle of the page  
5 there's an e-mail from Mike Reed to Mark Albrecht and to  
6 you. And in the middle of that he says:

7 "The infection reduction data has been given  
8 too much prominence. Whilst the data is real and can  
9 be used in the discussion, it is potentially controlled  
10 by many factors and I am not prepared to imply that  
11 this is solely an FAW effect. We have made lots of  
12 interventions -- it could be any, although I agree it  
13 could largely be a FAW effect."

14 Did I read that correctly?

15 A. Yes.

16 Q. Was he -- did you read that as having him trying to  
17 convince you that the infection data was being given too  
18 much prominence?

19 MR. SACCHET: Object to form.

20 A. You'd have to ask Mike Reed what he meant. I don't  
21 know what -- I don't know.

22 BY MR. C. GORDON:

23 Q. Well, you had expressed concern earlier, and Mike  
24 Reed is expressing concern about the infection reduction  
25 data being given prominence. You were part of the team.

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2 Was -- were you the driver, was Mike Reed the driver, or was  
3 Mark Albrecht the driver of including the infection data?

4 MR. SACCHET: Object to form.

5 A. I don't remember.

6 BY MR. C. GORDON:

7 Q. And --

8 A. Well, no -- well, the -- I did not originate  
9 including infection data into this paper, so I wasn't the  
10 driver of including it in the first place. I can say that.

11 Q. Is it your recollection that Mike Reed was?

12 A. I don't remember.

13 Q. In this e-mail Mike Reed says, "We have made lots  
14 of interventions -- it could be any." Do you see that?

15 A. Yes.

16 Q. What interventions that could have impacted  
17 infection rates were you aware of at this time?

18 A. It's very difficult to say, at this time, because  
19 as I said earlier, infection control in trying to reduce  
20 infection rates is an ongoing process in any responsible  
21 orthopedic department. Therefore, efforts to reduce  
22 infection are always ongoing. I can't, therefore, specify  
23 which interventions were made in this precise timescale. I  
24 can only speculate as to what those interventions might be.

25 Q. Did you think it was important, for a full



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2 understanding of the significance of the infection rates  
3 that you did report in the article, for the reader to  
4 understand all of the various interventions that had taken  
5 place?

6 MR. SACCHET: Object to form.

7 A. Did think it was important? Repeat that, please.

8 BY MR. C. GORDON:

9 Q. In the article that was ultimately published, you  
10 reported that the infection rate for the period of time when  
11 Bair Hugger only was being used was about 3.8 times higher  
12 than the seven-month period when HotDog only was being used?

13 A. Yes.

14 Q. Okay. The only interventions that you disclosed in  
15 the paper was a change in antibiotic prophylaxis and  
16 anti-thromboembolism prophylaxis; correct?

17 A. I don't remember the exact content of the paper but  
18 I do remember that both those were mentioned.

19 Q. And in fact they were mentioned because a reviewer  
20 had said "You need to mention them"; right?

21 MR. SACCHET: Object to form.

22 A. I don't recall what the reviewer said.

23 BY MR. C. GORDON:

24 Q. Do you feel -- did you feel, at the time, that if  
25 you were reporting a fairly dramatic drop in infection

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2 rates, nearly -- more than a 75 percent drop, that it would  
3 be important to appraise the reader of other interventions  
4 that had taken place during the Bair Hugger-only period that  
5 might have accounted for some of the infection reduction?

6 A. It's important to --

7 MR. SACCHET: Objection to form.

8 A. It's important to mention confounding factors,  
9 which is part of the whole purpose of not attempting to  
10 imply that this is causation, merely correlation.  
11 Confounding factors such as different types of  
12 thromboembolic prophylaxis, different antibiotic prophylaxis  
13 regimens, and any other measures that may be taken. So it  
14 is important to ensure that no claims are made which are not  
15 reasonable.

16 BY MR. C. GORDON:

17 Q. So if you say this doesn't necessarily show  
18 causation, is that, in your view, is that sufficient to  
19 disclaim any possible implication of causation?

20 MR. SACCHET: Object to form.

21 A. What's your question?

22 BY MR. C. GORDON:

23 Q. Well, you used the word "imply". There's obviously  
24 a difference between saying, "We have demonstrated  
25 causation" versus "We have demonstrated an association."

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2 Right?

3 A. Yes.

4 Q. And if you just say, "We've demonstrated an  
5 association", depending on what else you say about that, it  
6 could -- you could imply that there's a causal connection;  
7 right?

8 MR. SACCHET: Object to form.

9 A. Yes.

10 BY MR. C. GORDON:

11 Q. And if I understood what you just said, you wanted  
12 to avoid even implying that there was a causal connection?

13 A. I don't remember the precise words I used. What  
14 I mean to say is that I would not want to make a claim which  
15 was not reasonable in a paper, and based on the evidence  
16 that we had, I would not want to claim that there was  
17 a causation, or that we that proved or demonstrated  
18 a causation.

19 Q. Based on the evidence you had, do you believe it  
20 would have been reasonable to imply that there was  
21 a causation?

22 A. Um --

23 MR. SACCHET: Object to form.

24 A. Just repeat that again?

25 BY MR. C. GORDON:

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2 Q. Based on the evidence that you had, do you believe  
3 it would have been reasonable for your paper to imply  
4 a causal connection?

5 MR. SACCHET: Object to form.

6 A. If properly qualified, yes.

7 BY MR. C. GORDON:

8 Q. What would the proper qualifications be?

9 A. We -- if we have said that we believe, or think,  
10 that there is evidence that suggests that forced-air warming  
11 has an influence on infection, but that we recognize there  
12 are confounding factors, then that implication is tempered  
13 with the recognition that there are other effects that could  
14 be at play.

15 Q. And was it your intent, in your paper, to imply  
16 a causal connection?

17 MR. SACCHET: Object to form.

18 A. The intent was -- well, what the paper did was  
19 report a correlation.

20 BY MR. C. GORDON:

21 Q. And was it your intent, as one of the authors, to  
22 imply that that correlation represented a causal  
23 relationship?

24 MR. SACCHET: Object to form.

25 A. Was it my intent to imply that ... I don't know if

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2 you can separate implication and correlation. To imply  
3 a causation is to suggest a correlation. And I suppose  
4 you'd have to delineate very clearly what you mean by  
5 "imply", because I'm not sure I understand what you -- what  
6 you're referring to. An implication could be a suggestion,  
7 or it could be a claim that one -- that A affects B, but I'm  
8 not sure that we have established what you mean exactly by  
9 "imply" in this case.

10 BY MR. C. GORDON:

11 Q. I guess I'm just wanting to use the word as you  
12 used it, when you earlier -- your earlier testimony about  
13 implying.

14 A. Mm-hm.

15 Q. Let me see if we can approach this from another  
16 way. If you would take out volume 5, so I guess that's  
17 exhibit 7A.

18 A. 7A?

19 Q. Yes.

20 A. Volume 5, yes.

21 Q. If you turn to page 2419, this is identified as  
22 figure 7, showing infection data for 1,597 joint replacement  
23 cases with the average infection rate shown as a straight  
24 line from the vertical axis reflecting the Bair Hugger-only  
25 period, and then another line for the transition period,

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2 then another line for the conductive fabric period; correct?

3 A. Yes.

4 Q. That would be the HotDog-only period; right?

5 A. Yes.

6 Q. Now this version of figure 7 that we see on 2419,  
7 that would show an average infection rate during the  
8 HotDog-only period of roughly 1 percent or so, right?

9 A. Yes.

10 Q. And that's basically what you reported in the final  
11 publication; right?

12 A. Yes.

13 Q. Now if you turn to page 2262, that's an earlier  
14 version of this same figure 7, right? That only shows  
15 infection data for 1,290 joint replacement cases?

16 A. Okay.

17 Q. And at that point the cut-off looks like it was  
18 December 2010 as opposed to January 2011.

19 A. Right.

20 Q. And at this point it looks like it's showing  
21 a 0 percent infection rate for the conductive fabric for  
22 HotDog period; right?

23 A. Yeah.

24 Q. And now, if you would turn to page 2218, this is  
25 another version of figure 7, apparently covering the same

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2 period of time, September 2008 through September 2010; is  
3 that right?

4 A. Mm-hm.

5 Q. And also 1290 joint replacement cases?

6 A. Yes.

7 Q. But the data are presented differently in this  
8 figure 7; right?

9 A. Yes.

10 Q. Instead of an average infection rate across the  
11 entire time period, it's a moving average of infection rate  
12 plotted on the left-hand axis; right?

13 A. Yes.

14 Q. And in the version of figure 7 that appears on  
15 page 2218, in September 2008 the infection rate is about 3  
16 percent. It dips down over the next several months to  
17 somewhere around 2 percent, but then sometime after March of  
18 2009 it starts climbing up, and by sometime in between  
19 September 2009 and March of 2010, it's up to about  
20 4 percent; is that right?

21 A. That's what the graph shows, yes.

22 Q. And if you look at the little dots that are on top,  
23 those represent the actual incidents of infection plotted on  
24 a time axis; right?

25 A. Yes.

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2 Q. And where it starts heading up to 4 percent, that  
3 appears to be quite a cluster of infections right around  
4 those -- that several-month time period?

5 A. Yes.

6 Q. Do you recall that that several-month time period  
7 actually corresponded with the time that the hospital had  
8 switched to using rivaroxaban instead of the tinzaparin as  
9 the anti-thromboembolism prophylaxis?

10 A. I don't recall.

11 Q. Do you remember that there was a time the hospital  
12 switched from tinzaparin to rivaroxaban?

13 A. I am aware that there was a transition, yes.

14 Q. And do you remember that after some period of time,  
15 the hospital switched back to tinzaparin?

16 A. That sounds familiar to me. I wasn't aware that  
17 they had switched back wholesale. I knew that there were  
18 changes in thromboprophylactic medications.

19 Q. When did you leave Wansbeck?

20 A. It would have been about February 2010. Yes.

21 Q. Okay, so that would have been --

22 A. No, it might have been earlier. Around  
23 February 2010.

24 Q. And you don't recall, around the time that you were  
25 leaving, that there were -- hearing any conversations about



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2 "Wow, we've got a real spike in issues with this, with the  
3 rivaroxaban"?

4 A. I have a recollection that some patients who'd  
5 had -- well, various orthopedic operations, had more  
6 strike-through on their dressings, that is to say more ooze  
7 from post-operative wounds, but I don't remember any  
8 discussions about infection rates around that time.

9 Q. Why was figure 7, as it appears on 2218, changed to  
10 the flatline averages that appear in the subsequent ones,  
11 and the one that was ultimately published?

12 MR. SACCHET: Object to form.

13 A. I don't know.

14 BY MR. C. GORDON:

15 Q. Did you have any input into that decision?

16 A. No.

17 Q. Do you recall ever seeing the version that we see  
18 on page 2218?

19 A. I don't recall seeing it at the time. I've flicked  
20 through all of these documents but I don't remember  
21 a discussion around changing this, or the process of it  
22 being changed.

23 Q. And you don't recall anyone expressing the view  
24 that "Hey, the way it looks on" -- as we see it on 2218 --  
25 "it looks like there's some problem going on there in that

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2 last few months of the Bair Hugger-only period"?

3 MR. SACCHET: Object to form.

4 MR. C. GORDON: I actually need another exhibit  
5 sticker.

6 THE COURT REPORTER: Do you want me to mark it  
7 first?

8 MR. C. GORDON: Sure. Your handwriting is better.

9 A. I don't remember any discussions of that nature.

10 (Exhibit 11 marked for identification)

11 Q. Dr. McGovern, I'm going to show you what has been  
12 marked as exhibit 11. I'll give you a moment to look at  
13 that and see if you've ever seen it before.

14 A. It's possible that I've seen this, but I don't  
15 recall it.

16 Q. Do you know who Julie Jillson is, or Gillson?

17 A. I do not. I don't know who they are.

18 Q. So you don't know who Gail Lowdon is either?

19 A. No, I don't know who Gail Lowdon is.

20 Q. Okay. On the first page, I'm going to direct your  
21 attention to the very last paragraph where it says:

22 "During the last two quarters of 2008/2009,  
23 Northumbria Healthcare NHS Foundation Trust was  
24 reporting SSI rates in the combined total of surgeries  
25 in THR/TKR and Repair Neck of Femur between 3.5%-5% and

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2 was regularly receiving letters from the HPA informing  
3 the Trust of its high outlier status for SSI."

4 Did I read that correctly?

5 A. Yes.

6 Q. Does that trigger any recollections from when you  
7 started there, as to concerns that were -- that they -- that  
8 the Trust was in an outlier status in terms of its SSI  
9 rates?

10 A. It does. There were discussions and concerns about  
11 the infection rate, as I remember, in the Trust, and as a  
12 result, there was certainly an effort to implement good  
13 theater discipline to try to minimize the infection rate.

14 Q. Were you aware of any specific interventions that  
15 took place during the time that you were there?

16 A. Yes. I don't remember if they started before or  
17 after I arrived, but for example, in this healthcare trust,  
18 there was a red line beyond -- in the operating department  
19 beyond which you had to change into different scrubs. So  
20 frequently it's -- in some hospital trusts, it's standard  
21 to -- for doctors, or for healthcare professionals, to wear  
22 scrubs around the hospital and enter the operating  
23 department in the same scrubs. But on crossing the red line  
24 in Northumbria, one had to completely change, even if going  
25 in for 20 seconds. Even if you were going in to speak to

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2 someone. So there was a barrier.

3 All footwear was not individualized, it was --  
4 there were racks of new footwear provided in the special  
5 footwear-washing station, so footwear was washed every  
6 day. Particular attention was paid to good theater  
7 discipline, which is standard practice, but there was  
8 definitely a -- efforts were definitely made to maintain  
9 the very highest standards of care. And I don't  
10 remember any other specific interventions, but I'm sure  
11 there were more.

12 Q. Do you remember a time when the Trust implemented  
13 screening for methicillin susceptible staphylococcus?

14 A. It rings a bell. I don't remember at what time  
15 they did that. I don't remember a particular crossover  
16 point when screening for MRSA and MSSA was different, so  
17 I don't have a specific recollection of that happening,  
18 although it seems familiar to me to -- that MSSIs were --  
19 methicillin-sensitive staphylococcus aureus was screened  
20 for. I don't remember the specifics around that, though.

21 Q. Do you remember a time when the laminar flow system  
22 in one of the operating theaters was not functioning  
23 properly and had to be repaired?

24 A. I do not remember that.

25 Q. If you turn to the second page of exhibit 11, in

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2 the middle there it talks about -- the headline is "The SSI  
3 bundle."

4 A. Yes.

5 Q. And it talks about Patient Safety First published  
6 in SSI bundle in 2009.

7 A. Yes.

8 Q. Now if I could have another exhibit sticker.

9 (Exhibit 12 marked for identification)

10 I'm showing you what has been marked as  
11 McGovern exhibit 12. It's like a 32-page document  
12 called "The 'How to' Guide for reducing Harm in  
13 Perioperative Care, Patient Safety First."

14 I first ask if you recognize this document.

15 A. It's quite likely that I've come across it before,  
16 but I don't specifically recall it.

17 Q. Going back to exhibit 11, where it says "The SSI  
18 group decided to utilise this tool to develop a strategy to  
19 reduce the Trust's SSI rate."

20 Do you recall there being a period of time -- and  
21 you were there in 2009, right?

22 A. I was there from August 2009.

23 Q. Okay. So do you recall whether, while you were  
24 there, something similar to exhibit 12 was somehow  
25 distributed or utilized by the surgical staff?

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2 A. In terms of --

3 MR. SACCHET: Object to form.

4 A. -- in terms of documentation, not that I recall.

5 As I said, there was an acknowledgment in the department  
6 that the infection rate was higher than what would be --  
7 well, preferred, and there were efforts to reduce it, though  
8 I don't recall documentation to that effect, but there was  
9 certainly a cultural drive within the orthopedic department  
10 and within the surgical department in general, to minimize  
11 infection rates.

12 BY MR. C. GORDON:

13 Q. Do you recall a period of time when the type of  
14 wound dressings were switched?

15 A. I do recall that, yes, there was a different type  
16 of wound dressing used at some point. Yes, I do recall  
17 different wound dressings being used.

18 Q. Do you recall a wound dressing referred as to the  
19 Jubilee dressing?

20 A. I'd forgotten the name, but I remember vaguely the  
21 technique.

22 Q. What was your understanding of the reason for the  
23 change in wound dressing?

24 A. I think the dressing was -- I don't remember what  
25 the intention of the dressing was, apart from to make sure

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2 that it was as an effective a dressing as possible. But the  
3 appearance of it was one which was more robust than the  
4 predecessor. It was made of thicker material; it was more  
5 padded. But I don't remember what the rationale behind the  
6 switch was, in terms of what was theorized as the benefit or  
7 was marketed as the benefit of that dressing. I don't  
8 remember the process that went into that.

9 Q. Do you recall whether there was any research  
10 supporting the switch?

11 A. I don't, no.

12 Q. What's an Octenisan wash?

13 A. That is a wash which was given to patients to  
14 reduce the amount of naturally existing bacteria on their  
15 skin. The idea being that it would reduce the chance of  
16 them getting a postoperative infection.

17 Q. Is that different from chlorhexidine?

18 A. I don't know what the formulation of Octenisan is.  
19 I don't know what the active ingredient in that substance  
20 is. It could be chlorhexidine. It depends on the  
21 specific -- on what the manufacturing sheet says.

22 Q. Do you recall there being any kind of staff  
23 development training session on scrub technique?

24 A. As a surgical trainee, I was carefully monitored  
25 generally. So I'd received a lot of instructional scrub

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2 technique, and was expected to do it meticulously, and  
3 would. I don't remember being formally taught how to do it  
4 at Northumbria but I was very closely watched. And so to  
5 answer your question, I don't recall specific training that  
6 I received, although I may have -- someone may have taken  
7 a group of trainees aside and said, "This is how we want you  
8 to do it," but I don't remember.

9 Q. Do you remember there being a time when pre-warming  
10 of patients was introduced?

11 A. I remember it being discussed. I remember the  
12 principles being discussed of the importance of  
13 perioperative normothermia, that is keeping patients warm  
14 before and after and during surgery, the importance of that.  
15 And I remember that the idea of pre-warming was discussed.  
16 I don't remember if that was a new initiative or if it was  
17 something which was in place when I started at Northumbria.

18 Q. I'm not going to go through in detail all the other  
19 things that are referenced in exhibit 11, or the detailed  
20 timeline, but would you agree that to have a real  
21 understanding as to whether that apparent correlation that  
22 you recorded between switching from Bair Hugger to HotDog,  
23 and a reduction in infection rate, in order to have a really  
24 accurate understanding of that, a reader would have to know  
25 not just the change in antibiotics and anti-thromboembolism



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2 medications, but all of the interventions aimed at reducing  
3 surgical-site infections that we've just talked about?

4 MR. SACCHET: Object to form.

5 A. In the list of all the interventions one can make  
6 to reduce infection, I think the most important are the  
7 antibiotic prophylaxis, and I think in this case  
8 specifically, especially given the problems on that site, in  
9 that trust with rivaroxaban, those are by far the most  
10 important things to mention. One could argue that every  
11 intervention could be mentioned, but there is the question  
12 of, as authors of a paper, one wants to include every bit of  
13 detail that one can. But there is a tension between doing  
14 that and what the paper will publish, about what the journal  
15 will publish. There is a limit on how much information you  
16 can include in a paper, and space is at a premium. For some  
17 journals, for some disciplines, papers can be in extremely  
18 long form.

19 So for this type of paper, for this type of study,  
20 for this type of journal, I do think that confounding  
21 factors need to be mentioned, and I think that the most  
22 important confounding factors in this case have been  
23 mentioned, those being antibiotic prophylaxis regimens  
24 and thromboprophylaxis regimens.

25 Q. Well, given that you think those are the two most

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2 important, would you agree that the best way to see if they  
3 are confounding factors or not is to compare these infection  
4 rates, when the Bair Hugger was being used, with the same  
5 antibiotics and anti-thromboembolism drugs as were being  
6 used in the HotDog-only period?

7 MR. SACCHET: Object to form, foundation.

8 A. If I were conducting a study and I had complete  
9 control over such things, and it was ethically approved,  
10 absolutely. Controlling a single variable is ideal.

11 BY MR. C. GORDON:

12 Q. I'm talking about the same kind of observational  
13 retrospective study that you did do.

14 A. Right.

15 Q. If there was a period of time during the  
16 Bair Hugger-only period when the antibiotics and  
17 anti-thromboembolism regimen was identical to what was used  
18 in the HotDog-only period, would you agree that that would  
19 be a comparator that would eliminate those as confounders?

20 MR. SACCHET: Object to form, foundation,  
21 incomplete hypothetical.

22 A. It wouldn't eliminate them as factors, because it  
23 is extremely complicated, the factors that influence  
24 infection. However, it would be preferable to have  
25 a situation which you could have equivalent data and adjust

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2 one variable, or have only one variable change. That would  
3 be preferable in a retrospective study. Whether or not  
4 that's possible, that's questionable, but if that were  
5 possible, that would be preferable.

6 BY MR. C. GORDON:

7 Q. Okay. The period of time that you recorded for the  
8 HotDog-only period, that was seven months; right?

9 A. I believe so. I would have to check back through  
10 the paper to confirm that.

11 Q. However many months it was, the antibiotics that  
12 were being used were a combination of gentamicin and  
13 teicoplanin; right?

14 A. I would have to read the papers to confirm that.  
15 I don't remember, off the top of my head.

16 Q. Okay. For the purposes of my question, let's just  
17 assume that that's what your paper says.

18 A. Okay.

19 Q. A combination of gentamicin and teicoplanin. And  
20 for the anti-thromboembolism prophylaxis, it was tinzaparin.

21 A. Okay.

22 Q. Okay? Are you aware of whether there were any  
23 periods of time during that 23 months of Bair Hugger-only --  
24 or not 23 -- 20 months of Bair Hugger-only period when the  
25 same antibiotics and anti-thromboembolism drugs were being

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2 used on the Bair Hugger patients?

3 MR. SACCHET: Object to form.

4 A. I don't know.

5 BY MR. C. GORDON:

6 Q. Assume, for the purposes of this question, that  
7 there was such a period of time.

8 A. A period of time in which?

9 Q. The antibiotics being used were gentamicin and  
10 teicoplanin.

11 A. Okay.

12 Q. And the anti-thromboembolism drug was tinzaparin.

13 A. Okay.

14 Q. Would you agree that, if you looked at the  
15 infection rates from that period and compared them to the  
16 infection rates from the HotDog period, then you would have  
17 eliminated antibiotics and anti-thromboembolism as  
18 a confounding factor?

19 A. Over what period of time? Over seven months?

20 Q. Whatever period of time.

21 MR. SACCHET: Object to form. Incomplete  
22 hypothetical.

23 A. No, I don't think you could eliminate it, because  
24 to eliminate from a scientific standpoint would be to have a  
25 statistically significant result. And to have a

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2 statistically significant result for something as rare as  
3 infection requires a great number of cases. And what you're  
4 asking me is an opinion on whether the study was  
5 statistically powered sufficiently to demonstrate a change,  
6 and I don't know that, because I'm not a statistician. And  
7 I don't know what the numbers we're talking about are, and I  
8 don't know what statistical tests would be applied. So the  
9 answer to your question is, if there are sufficient numbers  
10 in one arm of the study compared with another, and they can  
11 demonstrate an effect that demonstrates statistical  
12 significance, then that will eliminate confounding factors  
13 if those confounding factors are adjusted for statistically.  
14 But I cannot speculate as to whether those factors would be  
15 eliminated here, because I don't have enough information to  
16 be able to do that.

17 BY MR. C. GORDON:

18 Q. So if you only -- if you didn't have enough time of  
19 Bair Hugger -- apples to apples -- to compare with HotDog,  
20 where the prophylanti -- where the antibiotics and the  
21 thromboembolism were the same, you don't see any problem in  
22 lumping in together, with the Bair Hugger-time period, the  
23 time when Bair Hugger patients were getting a completely  
24 different regimen?

25 MR. SACCHET: Object to form.

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2 A. It depends how it's described. If I were to -- if  
3 one word to misrepresent the data, that would be a problem.  
4 If one were to say that there were confounding factors, and  
5 this is what the data shows, then that's what the data  
6 shows.

7 BY MR. C. GORDON:

8 Q. With respect to misrepresenting the data, do you  
9 think that the figure 7 graph on 2218, where it is a moving  
10 average, is a better representation of the data than a  
11 flatline average over 20 months?

12 MR. SACCHET: Object to form.

13 A. Define "better".

14 BY MR. C. GORDON:

15 Q. Well, less -- strike that.

16 Let me ask the question the other way. Do  
17 you think showing a flatline average over a 20-month  
18 period, when there's obviously variation, as depicted  
19 on the earlier drawing, do you think that's a fair and  
20 accurate representation?

21 MR. SACCHET: Object to form and foundation.

22 A. It is a representation of the data, and it has  
23 been -- the data has been put into a statistical package and  
24 a graph has been produced from that. They are -- they both  
25 show the same thing in different forms, with different

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2 levels of resolution on the graph. They're -- the  
3 difference between taking an average over a day, or a week,  
4 or a month, they're averages. And to say one is better or  
5 not is a subjective thing. I don't really have an opinion  
6 on whether one is better than the other. Both graphs show  
7 a certain number of infections in one period and a certain  
8 number of infections in another period and transition  
9 period, and both are accurate, as far as -- to the best of  
10 my knowledge.

11 BY MR. C. GORDON:

12 Q. You don't think it is misleading to show, over  
13 a 20-month period, a flatline of 3 percent?

14 MR. SACCHET: Objection. Form, asked and  
15 answered.

16 A. Do I think it is misleading to represent the data  
17 accurately? Is that what you're saying?

18 BY MR. C. GORDON:

19 Q. To represent 20 months of infection data that  
20 varies, as we see on the earlier version of the graph,  
21 a flatline at 3.1 percent?

22 MR. SACCHET: Objection. Assumes facts over the  
23 evidence.

24 BY MR. C. GORDON:

25 Q. Over the entire 20-month period?

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2 A. But it's an average.

3 MR. SACCHET: Argumentative.

4 A. So if it's an average and it's representing over  
5 the average period, then it is accurate. So it's not  
6 misleading; it is accurate. And especially if the data  
7 there is -- the individual infection rates are there,  
8 I don't think they're excluded from the other graph. You'll  
9 correct me if I'm wrong, but they show the frequency of  
10 infections. So you can see, represented in graphical form,  
11 that there are a cluster of infections in September 2008 to  
12 early 2009, then relatively few, then a cluster later on.  
13 I think both graphs show that. But you'll correct me, I'm  
14 sure, if I'm mistaken.

15 MR. C. GORDON: We're running out of tape so we'll  
16 take a break here.

17 THE VIDEOGRAPHER: This is the end of DVD 2 in  
18 volume 1 in the deposition of Dr. Paul McGovern. Going off  
19 the record at 2:48.

20 (2:48 p.m.)

21 (Break taken.)

22 (2:59 p.m.)

23 THE VIDEOGRAPHER: This is the beginning of DVD 3  
24 in volume 1 of the deposition of Dr. Paul McGovern. Back on  
25 the record at 2:59. You're on the record, counsel.



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2 BY MR. C. GORDON:

3 Q. Thank you.

4 Dr. McGovern, if you could turn to page 288 in the  
5 e-mails volume 1.

6 MR. SHACKLADY: Which exhibit is that, Corey?

7 MR. C. GORDON: One.

8 MR. SACCHET: Do you mind saying the page again?

9 MR. C. GORDON: 288. This is an e-mail from Mark  
10 Albrecht to Dr. Oliver Kimberger and several other people  
11 including you; is that correct?

12 A. Yes.

13 Q. Do you know Dr. Oliver Kimberger?

14 A. I'm not certain I've met him. He was -- he's been  
15 on research that I've done, and I've corresponded with him  
16 through these group e-mails, but I don't recall ever meeting  
17 Oliver Kimberger.

18 Q. And you appear as a co-author on a paper with him?

19 A. Yeah.

20 Q. And in this e-mail -- it is titled "A little help  
21 'Sanitizing' this" -- Mark Albrecht says to Dr. Kimberger:

22 "Oliver.

23 "Thanks for your help on this. I think the  
24 research is good, but our conclusions appear to be over  
25 reaching. I'm sure you will be able to help us get

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2 back on track here.

3 "FYI -- Paul, Mike, and Bob, I've asked  
4 Oliver to help us sanitize the manuscript. Once he has  
5 done, we can try to re-submit elsewhere."

6 What did you understand Mark Albrecht to be  
7 telling you when he'd told you that he had asked Oliver  
8 to help "sanitize" the manuscript?

9 A. I don't know what Mark Albrecht meant by that.

10 Q. Did you ask him?

11 A. Not to my recollection.

12 Q. Did that strike you as kind of an odd use of  
13 a phrase for a scientific manuscript?

14 A. I don't recall.

15 Q. A little bit further down, there's an e-mail from  
16 Albrecht to Dr. Kimberger, where he says:

17 "Oliver.

18 "Say, would you be able to do me a small favor.  
19 I'm hoping you could go through the attached manuscript  
20 and identify what needs to be removed to get rid of the  
21 'agenda.' All of us at the company here are too close  
22 to this and are not being subjective as to what the data  
23 supports. We would be appreciative of any advice you  
24 can offer."

25 Do you see that?

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2 A. Yes.

3 Q. Did you have any idea, at the time, of what Mark  
4 Albrecht was talking about when he referred to the "agenda"?

5 A. I don't know what Mark Albrecht was talking about.

6 Q. Did you ask him?

7 A. Not to my recollection.

8 Q. If you could turn back to 2481, exhibit 7A.

9 I think it's that one. Actually, if you look at page 2480,  
10 I think that identifies the document.

11 A. "Outline of BHS presentation", yes.

12 Q. Okay. What is the "Outline of BHS presentation FAW  
13 vv CFW"?

14 A. This is a presentation that I gave to the British  
15 Hip Society, the precise date I don't remember. I think it  
16 was in Torquay in the south of England, and this was the --  
17 basically my script for the presentation.

18 Q. Did you actually give the presentation?

19 A. Yes.

20 Q. And there appear to be several comments along the  
21 right-hand side of the presentation?

22 A. Yes.

23 Q. "MRR" comments, those would be from Mike Reed?

24 A. Yes.

25 Q. And the "m" comments, those are from Mark Albrecht?

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2 A. I don't know. I'm sure there's a way of checking  
3 if that's certainly the case or not, but from what I see  
4 there, it just says "m". So without any further  
5 information, I couldn't say, because I don't remember.

6 Q. Okay. Number -- the comment m3, which appears to  
7 refer to the text:

8 "What might be responsible?

9 "- changes in infection reporting

10 "- changes in surgical practices

11 "- rise in drug resistant pathogens.

12 "- lastly, the adoption of forced air warming."

13 A. Sorry, drug resistant pathogens? M3? Where are  
14 we, page 2481?

15 Q. 2481.

16 A. Oh, I was reading the comments.

17 Q. If you look at M3, the dashed line over to the  
18 text, I was reading the text that it was commenting on.

19 A. Yes.

20 Q. And the comment is:

21 "I suggest you add this as an additional slide to  
22 focus the direction of where you are going in the  
23 broader context, that you are only looking at one  
24 potential factor among many possible culprits."

25 MR. SACCHET: Objection. Misstates the document.

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2 MR. C. GORDON: I wasn't finished, but --

3 MR. SACCHET: Well, it doesn't say "many".

4 MR. C. GORDON: Well then, I'll start again.

5 Thank you.

6 "I suggest you add this as an additional  
7 slight to focus the direction of where you are going in  
8 the broader context, that you are only looking at one  
9 potential factor among may possible culprits. This  
10 makes it look impartial and hides our agenda, so to  
11 speak ..."

12 Did I read that correctly?

13 A. Yes.

14 Q. And do you share my assumption that the "may" is  
15 a mistyped attempt at the word "many"?

16 A. I do. I read it as that as well.

17 Q. The last line there is what I want to ask you  
18 about. "This makes it look impartial and hides our agenda,  
19 so to speak." What did you understand your agenda to be  
20 that you were trying to hide?

21 A. My agenda?

22 Q. Well, the -- with the -- what -- who is the "our"  
23 referring to?

24 A. I don't know because I didn't write that.

25 Q. This is your -- these are comments on your

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2 presentation; right?

3 A. They are, but they're not -- that's not my comment.  
4 The comment by me would be "PDM".

5 Q. But when you read "This makes it look impartial and  
6 hides our agenda," what did you think that referred to?

7 A. I don't remember.

8 Q. Did that strike you as troubling, that somebody  
9 would suggest that you should try to make something look  
10 impartial, and hide an agenda?

11 MR. SACCHET: Objection to form.

12 A. Are you asking me if being impartial is troubling?

13 BY MR. C. GORDON:

14 Q. That somebody, whoever it was that made this  
15 comment on your draft, suggesting that you try to do  
16 something to make your presentation look impartial "and hide  
17 our agenda"?

18 A. I don't remember if that troubled me at the time.

19 THE COURT REPORTER: Sorry, was there an  
20 objection?

21 MR. SACCHET: Form.

22 BY MR. C. GORDON:

23 Q. Turn to the next page, 2482. In your text it says:  
24 "Our clinical concern is that there was a potential  
25 for hot rising air from the forced air system to disrupt

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2 laminar airflow, with possible consequences for airborne  
3 pathogenic contamination."

4 The comment from Mike Reed is:

5 "I'm tempted to say the driver for this was  
6 the need to verify the smoke DVD produced by  
7 Augustine -- remind them that this DVD was posted to  
8 all orthosurgeons in UK last year (assuming that is  
9 correct)."

10 Then the comment from "m7" is:

11 "I'd be careful here. That might imply  
12 a strong corporate agenda behind these activities and  
13 raise questions as to the credibility of the results."

14 When you read that, what was your  
15 understanding of why referencing in the Augustine smoke  
16 DVD might imply a strong corporate agenda behind these  
17 activities?

18 A. I don't know why referencing a smoke DVD that had  
19 been sent to all orthosurgeons would be concerning or --

20 Q. Do you know what that DVD refers to?

21 A. Yes I do, yeah.

22 Q. Have you seen it?

23 A. Yes.

24 Q. When did you first see it?

25 A. I don't remember when I first saw it. It was --

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2 I mean, around the time that I was at Wansbeck, but I don't  
3 remember where in the timeline my first seeing it lies.

4 Q. Was verifying that smoke DVD video the driver  
5 behind your bubble experiment?

6 A. Not to my knowledge. Not as far as I was aware.  
7 That wasn't my motivation for working on this project.

8 Q. Page 2486, and you've written:

9 "Notes - ? for discussion, or to fit into main  
10 body."

11 And the third one down is:

12 "Mention infection data from Northumbria."

13 And the comment from Mike Reed is:

14 "Suggest you hold this as the very last slide, one  
15 that is placed after your thank you slide at the end.  
16 If you are lucky you can steer a question to exposing  
17 it. Normally work a treat and can be introduced with  
18 'I thought you might ask that ...'"

19 Did I read that correctly?

20 A. Yes.

21 Q. Is that in fact how you presented it?

22 A. I don't remember if that slide was presented.

23 I think it wasn't. But that slide was put at the end of the  
24 presentation, but the reason for that being, as far as  
25 I recall, there's an extremely limited amount of time to



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2 present such research, I think six minutes or seven minutes,  
3 or something of that order, and they're extremely strict  
4 with time. And that's why I've written a script. Normally  
5 I wouldn't. Normally, I'd just present. But to make sure  
6 that I fit everything in that I wanted to, I was very clear  
7 about what I was going to say, when. And to put that extra  
8 slide in would have resulted in me running out of time or  
9 speaking too quickly, so as not to be clear. But after such  
10 presentations are given, there is time for questions. And  
11 so it was really something which I wanted to include, but  
12 you basically have extra time to present more slides if  
13 someone asks questions.

14 I think, in the event, the way that this  
15 presentation was organized was that all four presenters  
16 in the -- in my group presented sequentially, and then  
17 questions were asked of the whole group at the end. So  
18 I don't think I'd had an opportunity to present that  
19 slide. I think there was another slide, as well, in the  
20 presentation. It's likely that you have that  
21 presentation, actually, in the documents somewhere.

22 Q. If you could turn to 2494.

23 A. Yes.

24 Q. Where it says, "Bonus slide"?

25 A. Yes.

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2 Q. Is this, or something reasonably close to this,  
3 what you are referring to as the extra slide that you didn't  
4 have time to present?

5 A. This is -- yeah, I mean this does not look like  
6 a script; this looks more like notes. It looks like a later  
7 version, probably in response to the earlier comment. But  
8 yeah, this is a note of what I would say, were I asked about  
9 this, because if -- giving a presentation, I always try to  
10 anticipate questions that might be asked.

11 Q. Who is Dr. Imiak? And if you need help, look at  
12 2523. In there, I can point you to some more e-mails or  
13 some e-mails with --

14 A. Yeah, you may have to. I do remember the name, but  
15 I don't --

16 Q. I believe he's a doctor in Florida, perhaps.

17 A. Right. Yeah, I've seen the name before but I don't  
18 remember if I've conversed with him, communicated with him,  
19 or collaborated with him. I'm not sure.

20 Q. Did you end up doing any research activities in the  
21 United States?

22 A. I did, yes.

23 Q. Where?

24 A. The University of Minnesota in Minneapolis.

25 Q. Anything other than what you did at the University

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2 of Minnesota?

3 A. Research in the States?

4 Q. Yeah.

5 A. No, I think I've had one trip to the States for  
6 research purposes. I may have had two.

7 Q. Do you --

8 A. I think I've had one, and that was at the  
9 University of Minnesota. I'm pretty sure that's correct.

10 Q. I can dig them out, but there were some e-mails  
11 where Mark Albrecht was talking about doing a cross-country  
12 drive?

13 A. That's right. That didn't happen.

14 Q. And that didn't happen?

15 A. That didn't happen, sadly.

16 Q. What was the reason it didn't happen?

17 A. I think it was a logistics thing. I think he was  
18 getting equipment somewhere in a hospital, or an operating  
19 room being available or something. It was just  
20 a practicalities issue, as I remember.

21 Q. Could you turn back to page 155 now, in exhibit A.  
22 The volume you have in front of you, I think you can put it  
23 aside for the time being. Perhaps forever.

24 A. 155?

25 Q. Correct. 155, which is not fair, because it's in

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2 the middle. It's actually starts on -- it's a long e-mail  
3 chain.

4 A. 146?

5 Q. Is that the beginning of it?

6 A. It may be. I'm sure you'll correct me if I'm  
7 wrong.

8 Q. I think you're right. It's a long e-mail chain  
9 that starts at 146.

10 A. Yes.

11 Q. And this is a good deal of back and forth  
12 concerning one of your papers that was submitted to a  
13 publication, and these are reviewer comments?

14 A. Yes.

15 Q. And it's one reviewer comment in particular I want  
16 to direct your attention to, and that's page 155.

17 A. Right.

18 Q. At the top -- and I'm having trouble following what  
19 text is the reviewer comment, what text is people within  
20 your writing group offering comments.

21 A. I would imagine that anything which is in red or  
22 green is a comment, but I -- it is not perfectly clear, is  
23 it? I think the colored text is comments, but --

24 Q. And fortunately, what I want to ask you about is  
25 color, so we can probably assume that that's not a reviewer

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2 comment itself. It's specifically the line:

3 "Due to the clinical nature of these studies the  
4 authors were not able to assess contamination by wound  
5 wash out samples or by the use of airborne microbial  
6 sampling techniques such as a slit sampler."

7 Did I read that correctly?

8 A. You did. I think that might be -- that could well  
9 be a reviewer comment, because there's -- immediately below  
10 it, someone has written:

11 "Say to the reviewer 'We have addressed this point  
12 in the manuscript'."

13 So it looks like the formatting has gone wrong.  
14 But I think you read that correctly, but it looks like  
15 a reviewer comment to me, but I can't say with  
16 certainty, I'm afraid.

17 Q. Well, actually there are some other versions of it,  
18 so we can find that. If you look back at page 147.

19 A. Yes.

20 Q. Under "Reader 1" it says:

21 "The authors refer to the several publications that  
22 tend to disparage, or even deny, the efficacy of the  
23 clean air facility. None of the recent such  
24 publications are conclusive because not all sources of  
25 potential contamination are taken into consideration:

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2 the large New Zealand Registry findings are notable in  
3 this respect. Comment by the authors regarding the  
4 assessment of contamination by bacterial culture of  
5 wash-out samples or simple use of the slit sampler  
6 should be added, these being basic endpoints of air  
7 pollution."

8 Now if you flip to page 155, what I just read  
9 is there, but then it begins in a little bit different  
10 font:

11 "OK. I think we need to add the following to  
12 the text years. These studies have shown either an  
13 upwards trend towards or significantly higher infection  
14 rates in laminar flow."

15 A. Yeah.

16 Q. And it begins:

17 "Due to the clinical nature of these studies  
18 the authors were not able to assess contamination by  
19 wound wash out samples or by the use of airborne  
20 microbial sampling techniques such as a slit sampler.  
21 In these studies mobilization of non-sterile air with  
22 forced air warming may be the explanatory factor, since  
23 say to the reviewer 'we have addressed this point in  
24 the manuscript."

25 A. I'd agree, therefore, that this appears to be

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2 a comment by a researcher rather than a reviewer comment.

3 I would agree with that.

4 Q. And the way it comes together kind of looks like it  
5 is an iterative process with different people putting in  
6 different comments?

7 A. It's inconsistently formatted; I can say that.

8 Q. Do you know who wrote the "Due to the" -- it's  
9 actually "Due the the", to be correct:

10 "Due the the clinical nature of the studies the  
11 authors were not able to assess contamination by wound  
12 wash out samples or by the use of airborne microbial  
13 sampling techniques such as a slit sampler."

14 Do you know who wrote that?

15 A. I do not know who wrote that.

16 Q. In what way were these studies different than the  
17 study -- the very first study you did using a slit sampler?

18 MR. SACCHET: Object to form.

19 A. The -- okay. So the initial -- if we look at the  
20 bubble study in two parts, the section with the infection  
21 data is effectively an audit on patient activity, because it  
22 looks at data which has been collected anyway, and the  
23 experimental phase with the bubbles is an experiment.

24 This refers to the section which involved  
25 patients to the audit, and because this was looking at

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2 data which was collected anyway, i.e. infection rates  
3 which the Trust was looking at, there weren't, as I'm  
4 aware, programs to test washout samples, because that  
5 would have been a prospective study design. That would  
6 have been one in which it was pre-planned to look at  
7 washout samples. Now, maybe that data was available,  
8 but I don't know.

9 In terms of a slit sampler, we did not have  
10 what I understand to be a slit sampler. We did have  
11 a -- the type of sampler which has been discussed in  
12 the first experiment, but a slit sampler is slightly  
13 different. It's one that we had discussed using, and  
14 we had tried to get hold of one but they were very  
15 expensive and we couldn't get hold of one, so we used  
16 the one which we ended up using which was, to my  
17 understanding, seen as less good. I don't know if that  
18 answers your question.

19 BY MR. C. GORDON:

20 Q. Is there any reason, when you were doing the bubble  
21 experiment, you couldn't have used a slit sampler?

22 A. Yeah, well a slit sampler, if we had access to one,  
23 potentially, because it's a much -- it's a large machine  
24 which has a very small inner nozzle attached to a hose, so  
25 it wouldn't disrupt the positioning of personnel, the model



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2 patient, very much. But as you see from the images from the  
3 previous study, it was quite a bulky machine that needed to  
4 sit on a table next to the operative field, which itself  
5 causes air disruption. So, in itself, it is an unrealistic  
6 model or an unrealistic component of a sample operation.

7 In addition, it would be less relevant to use  
8 a bacterial sampling technique in an operating room  
9 which isn't having an operation going. The purpose of  
10 the bubble experiment was to look at airflow, was to  
11 look at how air flows around the room. And without any  
12 movement, you know, because there was no skin -- it was  
13 a mannequin that was used in those experiments --  
14 you're not disrupting and moving bacteria from  
15 a patient; and so it would have required a significant  
16 change in study design, which would have probably  
17 reduced the value of air-movement data that we  
18 collected.

19 You could use a slit sampler for clinical  
20 studies. I think there have been papers in which slit  
21 samples or similar devices have been placed near  
22 patients to look at contamination, but we didn't have  
23 one, and that would require ethical approval and would  
24 be researched, because you would be introducing a -- an  
25 object to the operating room which could potentially

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2 get in the way, that would need its own risk  
3 assessment, its own hazard assessment of any harm to  
4 the patient, any compromise in the way the operation  
5 was conducted. And that was not what we were doing.

6 Q. In your bubble study, when you turned on the  
7 HotDog, how long did -- was the HotDog on before you started  
8 using the bubble wand?

9 A. I don't remember the precise time, but before each  
10 run, everything was allowed to warm up and get to  
11 temperature. So I don't remember the precise times, but  
12 I do remember that the runs were randomized. So we didn't  
13 choose which order the different protocols went in. And  
14 there was a warm-up period for everything, so there was --  
15 the actual data collection was a small slice of the total  
16 time for each run, because there was a period of setting the  
17 experiment up, making sure everything was similar to  
18 previous runs, and then allowing things to get to sort of a  
19 steady state.

20 Q. On the video that has been posted on your blog of  
21 the bubble experiment, there's like a tube or a wand?

22 A. Yes.

23 Q. Who is holding that?

24 A. I don't remember who is holding that. There were  
25 lots of videos taken. I mean, if you showed me, I'd

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2 probably be able to tell you, but I don't remember who in  
3 that video, on the blog, had the wand in their hand.

4 Q. And how was it determined what the angle of that  
5 wand should be, relative to the heating device?

6 A. The angle wasn't determined. Basically, the way  
7 the bubbles work is that they're neutral density. That  
8 means they hover, suspended in still air. So if there is  
9 zero airflow in a room, a helium bubble will hang there  
10 motionless. If it's positive density, it sinks, and if it's  
11 negative density, it rises. And these bubbles are  
12 configured so that they're neutral density, so they hover  
13 there. So when air flows anywhere in the room that disturbs  
14 the bubble, it moves. It moves, and the idea is that it  
15 represents where air is flowing.

16 And so, to my understanding of how the bubble  
17 machine works, the angle of attack, as it were, the  
18 angle of the outlook port of that bubble machine,  
19 doesn't really matter. It may make a tiny difference,  
20 but because the bubbles are so very light and because  
21 they are neutral density, any airflow will overcome the  
22 momentum that they have coming out of the bubble port  
23 fairly quickly.

24 Q. What is the velocity of the bubble coming out of  
25 the port?

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2 A. I don't know what the velocity of the bubbles  
3 coming out of the port is.

4 Q. They have some momentum; right?

5 A. They have some, yeah. They are moving when they  
6 come out of the outlet, because that's how they get from the  
7 machine to the air.

8 Q. And to the -- to your point of the angle of attack,  
9 if there's momentum, even if they're neutrally dense,  
10 neutrally buoyant, if the angle is such that, with its  
11 momentum it hits something, that's going to deflect --

12 MR. SACCHET: Objection --

13 BY MR. C. GORDON:

14 Q. I don't remember the formula any more. You did  
15 A-level physics.

16 A. I did. That would be the case if flow were  
17 laminar. Laminar flow means if you -- it means the flow is  
18 in a predictable pattern from an outlet. But the flow from  
19 that outlet in question is likely to be turbulent, so it is  
20 likely that if you look at any particle coming out of  
21 a bubble generator in a room with no airflow, it's likely  
22 that their movement will be quite random. It's likely that  
23 they would not just come out in a steady stream, because the  
24 nature of the airflows at low velocity and the nature of the  
25 outlet is such that it's, as I understand it, not designed

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2 to produce a laminar flow. It is designed to produce --  
3 well, it just produces a turbulent flow of bubbles. So it's  
4 not really possible to predict how each individual particle  
5 will react when it comes out of the outlet.

6 Q. At some point --

7 A. Suffice to say, it's not likely to go back in.  
8 It's likely to come out in some direction, but it could go  
9 up, it could go down, it could go forward. It depends on  
10 the external conditions.

11 Q. But at some point it has a laminar flow to it  
12 before it becomes turbulent; right?

13 A. It will do when it is in the pipe, but --

14 MR. SACCHET: Object to form.

15 A. -- but when it's out -- and bear in mind that I'm  
16 not an aerodynamicist or a flow physicist, so -- but my  
17 understanding of it is that the flow becomes turbulent very  
18 shortly after exiting the outlet unless it's taken up by  
19 a laminar flow system, or unless it's influenced by  
20 something else. But I don't know what the zone of -- I  
21 don't know at what point the influence of the bubble machine  
22 stops or reduces, and the influence of the external  
23 environment takes over. I don't know if it's an exponential  
24 decay or if it's a linear decay in terms of the influence.

25 I mean, going back to your original question,

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2 the bubble generator was, from my memory of the video,  
3 was generally held at a fairly horizontal sort of  
4 level. It was held at hip height. There were some  
5 other videos done in which it was held above head  
6 height, but that wasn't with specific relation to  
7 warming blanket technology. That was looking at the  
8 overhead operating lights and their influence on  
9 laminar flow. But from my memory of those videos, the  
10 outlet was relatively horizontal, but there may have  
11 been 5, 10, or more degrees deflection, because that  
12 was not -- that video is of us seeing what effect we  
13 could observe with that equipment in that situation.

14 BY MR. C. GORDON:

15 Q. Was the -- in the set-up, did you -- had you draped  
16 off the heating units, whether it was the Bair Hugger or the  
17 outlet?

18 A. What do you mean? Do you mean in the experimental  
19 set-up, or?

20 Q. Yes.

21 A. Yes. In the experimental set-up they were draped  
22 as close to reality as possible. So it was, for this  
23 experiment, it was a mannequin which had flexible limbs, so  
24 it could be positioned relatively realistically, although  
25 there are always going to be differences between mannequins

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2 and humans. But the draping technique was as it would be  
3 for hip replacements or knee replacements, or the operations  
4 that we were doing. We tried to use exactly the same drapes  
5 and use the same draping techniques that we would for a real  
6 patient.

7 Q. I want to turn to page one seventy -- so where  
8 does it start? It looks like it starts at page 174. This  
9 is -- it looks like an e-mail chain addressing a rejection  
10 from the Journal of Hospital Infections.

11 A. Mm-hm. Sorry, yes.

12 Q. And -- I won't go through the comments, but I want  
13 to turn to page 177. This is in response to somebody  
14 suggesting that this paper be submitted to Anesthesiology.

15 Mark Albrecht writes:

16 "Oliver.

17 "Yea, Anesthesiology is a very tough journal to get  
18 into, but that also makes them a thought leader."

19 If you jump down, that same paragraph:

20 "They might very well reject this at first  
21 pass also, but it's worth a shot before we just dump  
22 this into a nursing journal or something like that."

23 Do you see that?

24 A. I do see that.

25 Q. And where was this paper ultimately published? Do

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2 you recall?

3 MR. SACCHET: For the record, can we establish  
4 which paper we're talking about?

5 BY MR. C. GORDON:

6 Q. Do you know which paper this was?

7 MR. SACCHET: I can tell you, but I'm not going  
8 to.

9 (Reporter clarification.)

10 A. This paper, going over to page 175, appears to  
11 refer to "An Evaluation of Intake Filtration, Internal  
12 Microbial Build-Up, and Airborne-Contamination Emissions."

13 I have a suspicion this was published in Anesthesia  
14 and Analgesia, but I'd need to check. I can't remember.

15 Q. Do you recall this being referred to by Mark  
16 Albrecht as "The European Crud and Bug Study"?

17 A. That term has been used, but I don't remember if  
18 that specifically refers to this paper.

19 Q. Do you recall any paper in which you were an author  
20 being published in the American Association of Nurse  
21 Anesthetists Journal?

22 A. It may have been, but I can't remember.

23 Q. In August of 2013?

24 A. I can't always remember the journals they are  
25 published in. So it seems plausible, but I'd need to check



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2 and actually look.

3 Q. Do you know if the American Association of Nurse  
4 Anesthetists Journal is a nursing journal into which you  
5 could "dump something", to use Mark Albrecht's phraseology?

6 MR. SACCHET: Object to form.

7 A. I have no idea.

8 BY MR. C. GORDON:

9 Q. Down at the bottom of 177, this is April of 2011,  
10 it says -- it is from Mike Reed to Mark Albrecht, and it  
11 says:

12 "Mark. The letter of submission reads well  
13 although I am not sure how much influence these letters  
14 have.

15 "My conflicts are departmental funding of  
16 unrelated research from Augustine Temp Management (£5K  
17 if they need that). No personal gain."

18 Do you have any idea of what the unrelated  
19 research from Augustine Temp Management of £5,000 was  
20 that Mr. Reed was referring to?

21 A. I don't, although you mentioned earlier today that  
22 there was a sum of £5,000 received for another study.  
23 I would assume it was referring to that, but I don't --  
24 prior to what you've said to me earlier, I had no knowledge  
25 of that sum in relation to this, or what is being referred

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2 to specifically in this e-mail.

3 Q. If you'd turn to page 178, at the very bottom  
4 there's an e-mail from you to Mark Albrecht with a copy to  
5 Reed and Kimberger, where you say:

6 "I can't see anything objectionable in the  
7 paper, it looks good. I've put a couple of suggested  
8 changes in the cover letter, they make it sound a bit  
9 less partisan to me."

10 What did you mean by "a bit less partisan"?

11 MR. SACCHET: Object to form.

12 A. What I'd mean is that if language in a paper sounds  
13 partisan, or biased, that's generally something that  
14 would -- one would wish to avoid. And I don't remember the  
15 specific suggested changes, perhaps they're in -- perhaps  
16 you have a reference to them -- but my aim would always be  
17 to take a neutral tone in a paper, where appropriate, and so  
18 that is what I believe I was referring to there. It may  
19 have been that the language did not take what I considered  
20 to be the appropriate tone, and I made an adjustment to that  
21 effect.

22 BY MR. C. GORDON:

23 Q. Turn to page 283, please. It's an e-mail from Mark  
24 Albrecht to you and Mr. Reed.

25 A. Yes.

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2 Q. With a carbon copy to several other people, and it  
3 is entitled "Publication Factory Continues"?

4 A. Yes.

5 Q. What did you understand the Publication Factory to  
6 be, when you got this e-mail?

7 A. I don't remember what I thought of it at that time,  
8 but what I understand by it now is that the research effort  
9 was producing several publications; and this was in  
10 reference to that ongoing effort to produce publications.

11 Q. And the writing was primarily coming out of Mark  
12 Albrecht and his colleagues at the Augustine Company; right?

13 MR. SACCHET: Object to form.

14 A. Sorry, you were saying the writing was -- what was  
15 the question?

16 BY MR. C. GORDON:

17 Q. Where was the Publication Factory?

18 A. I'm not sure there was a physical location.

19 Q. Turn to page 398, please. It's an e-mail from  
20 Scott Augustine to Robert Gauthier, Mike Reed, you,  
21 Professor Nacathsheim, and a carbon copy to Mark Albrecht.  
22 And in this e-mail Dr. Augustine says:

23 "Bob, Mike, Paul, and Chris,

24 "Mark asked me to pass on this completed draft to  
25 all of the authors after I made any last minute changes

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2 (see attached)."

3 Why was Scott Augustine making changes to  
4 your publication?

5 MR. SACCHET: Object to form.

6 A. I don't recall.

7 BY MR. C. GORDON:

8 Q. Does it strike you as odd that the owner of  
9 a company that manufactured a product that stood to benefit  
10 by research, that raised safety issues about its competitor,  
11 was finalizing a draft of your independent research and  
12 sending it to you?

13 MR. SACCHET: Objection. Argumentative. Move to  
14 strike to preamble.

15 A. Where would you -- you said "finalize a draft".  
16 Where is that?

17 BY MR. C. GORDON:

18 Q. Complete a draft. The completed draft.

19 A. Right, but Scott Augustine can send any e-mail that  
20 he wants to. That doesn't mean that that's what was  
21 submitted. I'm not sure if that was or not, but Scott  
22 Augustine is free to send whatever he wishes.

23 Q. So when you got this, it didn't strike you as odd  
24 that Scott Augustine was sending you something that he  
25 described as a completed draft to all of the authors after

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2 he, Scott Augustine, had made last minute changes?

3 A. It doesn't strike me as odd. I think that I, on  
4 receiving an e-mail like this, I would be mindful of the  
5 potential conflict of interest, and I would be keen to  
6 review what changes were made, to establish if the message  
7 of the paper was still what I and my colleagues, as  
8 scientists, felt was appropriate. It didn't strike me as  
9 odd that someone who is involved in an e-mail chain  
10 regarding a paper would suggest changes, but -- yeah, it  
11 doesn't strike me as odd inherently, because this is not  
12 finalizing a draft. This is not the last say on what is  
13 finally submitted.

14 MR. SACCHET: Can we clarify which paper we're  
15 talking about, for the record?

16 BY MR. C. GORDON:

17 Q. Do you know which paper this refers to?

18 A. I do not. You would have to look for "Cover Letter  
19 8-25.doc" and "manuscript\_\_Laminar\_\_8-25.doc" because that  
20 will have the relevant paper.

21 MR. SACCHET: I'll excuse the speaking objection,  
22 but it is an unpublished laminar-flow paper that was never  
23 published in the journal.

24 BY MR. C. GORDON:

25 Q. Can you turn to page 574, please.

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2 A. Yes.

3 Q. And this begins a several page e-mail chain  
4 starting on March 25, 2016.

5 A. Yes.

6 Q. From Robin Humble to Scott Augustine and to you,  
7 with a carbon copy to Steve Hammant-Stacey. First of all,  
8 remind me again who Robin Humble is?

9 A. Robin Humble is -- works, I think, as a sales  
10 representative for Augustine, or he works in distribution  
11 for Augustine products, as far as I'm aware.

12 Q. Had you had any pre-warning or pre-notice that  
13 you'd be hearing from Robin Humble before you got this  
14 March 25, 2016, e-mail?

15 A. Not to my recollection. No, I don't think so.

16 Q. Okay. And he tells you that Scott Augustine wants  
17 to contact you; right?

18 A. Yes.

19 Q. And your reply is that -- you tell him where you're  
20 working now, and that you look forward to hearing from  
21 Scott; right?

22 A. Yes.

23 Q. And drop to the very bottom, on March 28 Scott  
24 Augustine e-mails you directly and says:

25 "Hi Paul, it has been a long time! I hope

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2 that all is well with you."

3 Then it goes on for a page and a half or so;  
4 right?

5 A. Yes.

6 Q. And if you turn to page 576, he -- after discussing  
7 what's happening with the Bair Hugger litigation and things  
8 related to your original paper, the bubble paper, he says:

9 "... I took the liberty of knocking out  
10 a first draft of a possible paper recording your data  
11 (attached). My question is simple -- would you be  
12 willing to edit, change, add or subtract as you see fit  
13 and then be the author? My name tends to be  
14 distracting in situations and therefore I prefer not to  
15 be an author -- I'll have to stick with being an  
16 inventor. If Mike would want to join you, that would  
17 be great."

18 Did I read that correctly?

19 A. Yes.

20 Q. And attached to this was a fully drafted paper with  
21 your name on it?

22 A. Yes.

23 Q. That you hadn't written?

24 A. Correct.

25 Q. Did that surprise you, when you got it?

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2 A. I wasn't expecting it.

3 Q. And having received it, did it in any way disturb  
4 you that Dr. Augustine would write a paper and put your name  
5 on it, and then send it to you?

6 A. It didn't disturb me. It would disturb me if  
7 I found it in a peer-reviewed journal under my name. That  
8 would disturb me. But sending me a draft with my name on it  
9 isn't something that I would do. It is a little more  
10 forward than my personal style would be; but it's a document  
11 to me, with a suggestion. So I wasn't expecting it, but it  
12 didn't disturb me, no. If my name had been misrepresented  
13 and it had been stated that I had written it, in public,  
14 then that would have been an issue. But it wasn't.

15 Q. So Scott Augustine writing up a paper and putting  
16 your name on it and sending it to you, that's kind of what  
17 you expect out of a publication factory; right?

18 MR. SACCHET: Objection to form. Argumentative.

19 A. No. As I said, I didn't expect it.

20 BY MR. C. GORDON:

21 Q. And how did you respond to Dr. Augustine's inquiry?

22 A. I forwarded the e-mail to Mike, telling him my  
23 inclination is not to do this, and not to be involved at  
24 this stage. But that I thought -- sorry, Mike Reed. But  
25 I thought it was worth drawing to his (Mike's) attention.



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2 Q. In fact, on page 577 you said, after telling him  
3 your inclination was "not to do it at this stage," you said:

4 "Just to be clear, I have had zero input on the  
5 attached paper, despite my name being on the top. Scott  
6 sent this to me."

7 A. That is correct.

8 Q. Why did you want to be clear about that?

9 A. Because I had zero input on that paper. Because  
10 that was fact, and I didn't want to give the impression  
11 that I had written it. I hadn't actually read the paper in  
12 any detail. I had read the name of the -- I still haven't  
13 read it in any detail. I skimmed it and sent it to Mike,  
14 because, as I said in the e-mail, my inclination was "not to  
15 do so at this stage". And so I thought Mike would be  
16 interested -- Mike Reed would be interested, so I sent it to  
17 him.

18 Q. So you told Augustine that you'd forwarded it to  
19 Mike; right?

20 A. I'm not sure if I told -- I don't know if I told  
21 Augustine. I'm pretty sure I told him that I'd discussed it  
22 with Mike.

23 Q. Look at 578. It is an e-mail from you to  
24 Augustine. You say:

25 "With regards publishing further forth in

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2 orthopedics, it's not really my area any more. I've  
3 contacted Mike and forwarded him the draft."

4 A. Right, so I did. I did tell him that I'd forwarded  
5 Mike the draft, yes.

6 Q. And he got back to you on April 4 and said:

7 "Interesting. I'm reviewing periop hypothermia for  
8 nice so don't want to embark on any related research at  
9 the mo. Likely that this will come out in any  
10 depositions anyway. We did analyse this before and  
11 I presented it at the Mayo (I think) as one of their  
12 anaesthetists raised it ahead of a PPT I did there. It  
13 looked like antibiotics has no effect. Tell Scott to  
14 fund an RCT. One has been designed in the uk but I'm  
15 not leading on it."

16 Did I read that correctly?

17 A. Yes.

18 Q. Did you have any communications there with Scott  
19 Augustine about Reed's situation?

20 A. I have mentioned to Scott Augustine that he didn't  
21 really want to be involved, that he wasn't able to be  
22 involved. I -- yeah, I did mention that to Scott. I can't  
23 remember how or when, but --

24 Q. Was that in a phone call?

25 A. It may have been in a phone call. I don't remember

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2 if it was an e-mail or phone call, or both.

3 Q. On page 580 you, in an e-mail to Reed, you say  
4 that:

5 "I will probably go ahead and work with Scott on  
6 this on my own then, if you've no objections."

7 A. Yes, I did say that.

8 Q. And have you done anything further with Scott  
9 Augustine since April 4?

10 A. So I've had a conversation with Scott Augustine and  
11 he has -- I said to him that I considered being involved,  
12 because the concern with the data, the reason that I sent  
13 this to Mike is, as I said before, I didn't really have  
14 anything to do with the section of my paper -- or I had  
15 something to do, but I didn't lead on the section of my  
16 paper which was involved with this data, with the infection  
17 data. And so I wanted to get some more information, but  
18 I said I wouldn't be happy to publish it without it being  
19 very clear that any publication came from Scott Augustine.  
20 If there was -- I wasn't prepared to be involved if -- and  
21 to try and -- if there was any appearance that we were  
22 trying to not disclose that there had be involvement from  
23 the Augustine company.

24 Q. How did you communicate that?

25 A. It was -- I -- it was either a telephone call or an

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2 e-mail. I can't remember which.

3 Q. On page 580, at the very bottom, there's an e-mail  
4 from Robin Humble to you on June 17, 2016?

5 A. Yes.

6 Q. Where he says:

7 "Hi Paul,

8 "Hear you're going to meet with the  
9 Augustines on Sunday?"

10 A. Yes.

11 Q. Did you meet with the Augustines?

12 A. Yes.

13 Q. Was that in England?

14 A. Yes, they were in England for some -- they had  
15 several meetings, and they were very close to where I live,  
16 where they were staying in London, so I met up with them.

17 Q. That was Sunday in mid-June of 2016?

18 A. Yes, yes.

19 Q. Where did you meet them?

20 A. Euston Square.

21 Q. Is that a restaurant?

22 A. At their hotel, and then we had a meal at the  
23 restaurant.

24 Q. Did you discuss any of the research stuff?

25 A. Yes. So we would have discussed this at that

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2 meeting as well as in a phone call, or any e-mails we may  
3 have had.

4 Q. And have you had any communication with Augustine,  
5 Scott Augustine -- well, yeah, since then? Since that  
6 dinner?

7 A. Yes, so I -- my recollection is that at or around  
8 this point, either of arranging this meeting or having this  
9 meeting, I made clear that I wouldn't be involved unless it  
10 was very clear that Scott Augustine's company was involved,  
11 and that -- Scott Augustine said that he would put me in  
12 touch with a colleague of his who would be happy to work on  
13 the paper. My thought of this was that I didn't really have  
14 a problem with reporting this data, but I'd need to  
15 completely rewrite the paper, as in start from scratch and  
16 look at the data go and through the whole process. So I was  
17 quite cool on the idea because it's, as I've said in this  
18 e-mail, I'm out of that area of practice, and I don't need  
19 publications in orthopedics any more for my career. I'm not  
20 particularly motivated to do this sort of work.

21 And while a publication is always a string to my  
22 bow, and always useful to have, because it had been  
23 written and my name had been put on it, I was thinking  
24 that if I were to be involved in the project in any way,  
25 the involvement of Augustine's company would have to be

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2 very clear, and I would have to rewrite it. So I would  
3 have to completely redo the paper and have to discuss  
4 with Mike Reed the relevance of any infection data. And  
5 it seemed to me that this was not really something which  
6 I was that interested in doing, because it would take a  
7 lot of effort.

8 Q. Why was it important to you to make sure that it  
9 would be really, really clear that Augustine's company was  
10 involved?

11 A. Because it would be a potential conflict of  
12 interest. It's important that if -- if research involve --  
13 research involves an author with a potential conflict of  
14 interest, that that is declared in the peer-review process.

15 Q. Why don't you turn to page 587. It is an e-mail  
16 from June 11, 2016, from Scott Augustine to you.

17 A. Yes.

18 Q. Where he introduces you to Dr. Tom Durick?

19 A. Yes.

20 Q. Who is Dr. Durick?

21 A. I think he's an anesthesiologist. I've never met  
22 him. I think I might have exchanged a couple of e-mails  
23 with him, but -- I don't know if there's any more than this,  
24 but really not more than one or two more than this. So I've  
25 never met the guy.

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2 Q. Was Dr. Durick the person that Dr. Augustine had  
3 said he was going to introduce you to?

4 A. Yes, I think so. I wasn't aware of the name at  
5 that time, but this followed on from that conversation, or  
6 those conversations, yes.

7 Q. And what's happened with that?

8 A. Nothing. Tom Durick hurt his arm or his shoulder  
9 or something, and didn't answer any e-mails for a while, and  
10 Scott sent an e-mail saying, "What's going on with this?"  
11 And I might have e-mailed Tom, and Tom e-mailed me, and then  
12 it's just sort of gone by the wayside, and nothing has come  
13 of it. I haven't -- I still haven't read the draft paper in  
14 its entirety, and I don't really have any interest, now, in  
15 getting another paper, because I have other projects to do  
16 and other research that is more interesting to me.

17 Q. The latest e-mail -- and I could be wrong, but the  
18 latest e-mail I see in what you produced -- was June 12,  
19 2016. Do you think you've had e-mail communications either  
20 with Augustine or Durick since June 12?

21 A. Yeah, I think -- yeah, I think -- I can't remember  
22 if I've spoken to -- I don't think I've ever spoken to Tom  
23 Durick on the phone. I might have done, but I don't think  
24 so. I might have spoken to Scott Augustine, but I think  
25 there's been one more back and forth, or -- because I don't

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2 think it says here that Tom Durick hurt his shoulder or  
3 something, and I somehow know that. So there's been some  
4 communication at some point, but not in any detail, not  
5 actually progressing towards any sort of plan.

6 Q. Where do you think it stands now, in the eyes of  
7 either Dr. Durick or Scott Augustine?

8 MR. SACCHET: Object to form.

9 A. I don't know how it stands in the eyes of  
10 Dr. Durick or Scott Augustine. In my eyes, it is something  
11 which is suggested, but I don't particularly have an  
12 interest in taking it forward. It is possible that I will  
13 at some point in the future become interested in it, but  
14 I have quite a lot of things on, and I can't really see this  
15 rising to the top of the piles of work that I have to do, to  
16 the extent that I complete it.

17 BY MR. C. GORDON:

18 Q. I'd ask you to turn to page 609. It is an e-mail  
19 from you dated August 27, 2013.

20 A. Yes.

21 Q. To Mike Reed, and the heading is "Brandon Meeting"?

22 A. Yes.

23 Q. What does "Brandon" refer to?

24 A. Brandon is --

25 Q. I don't know if it is Brandon or Bradford, because



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2 there is "Bradford" in the text?

3 A. Yes. So Brandon, as I remember, is a company based  
4 in Bradford. A city.

5 Q. Okay.

6 A. And I can't remember why I contacted these guys.  
7 I think I contacted them in the first place, but I seem to  
8 remember that they had operating lights which they  
9 advertised as being less disruptive to laminar flow than  
10 other designs. And so I got in touch with them, and  
11 I can't -- I went to a meeting and spoke to this Adrian Hall  
12 and someone else; there was a prof at a meeting. I had  
13 a chat with them about possibly doing some research into  
14 airflow -- the effect that operating lights have on laminar  
15 airflow. And we discussed the possibility of doing some  
16 research in an experimental operating room that this company  
17 was talking about building, but it never really went to  
18 anything. We had one, maybe two, meetings, a couple of  
19 e-mails exchanged, and it didn't really go anywhere.  
20 Although I have since done some research into the influence  
21 that overhead operating lights have on laminar airflow; but  
22 not with this group.

23 Q. There's one line in particular I want to ask you  
24 about.

25 A. Mm-hm.

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2 Q. In this e-mail at the second-to-last paragraph, you  
3 say:

4 "Not in a great rush to do that as I think equating  
5 particles to bugs should come first."

6 A. Yes.

7 Q. What do you mean by that?

8 A. I can't remember what I meant by that. But it's --  
9 particles can only ever be a model, and I was aware that the  
10 videos that we've done show bubbles moving into operating  
11 wounds, but that did not mean that bacteria were going into  
12 operating rooms -- into wounds, necessarily. And so  
13 I think, for the progress of this research, it is worth  
14 developing a model which shows how particles deposit, what  
15 type of particles carry organisms which may cause infection,  
16 and how they can be tracked. But I'm not sure I agree with  
17 myself in terms of saying "equating particles to bugs should  
18 come first." I think it is an important thing to examine,  
19 but if -- in the event the next piece of research that I  
20 did, or the most recent piece of research I'd done in this  
21 area was looking at, again, particles or bubbles as a marker  
22 for particles which could act as vectors for infection.

23 Q. If you turn to the next page, there's a continuing  
24 back and forth between you and Mr. Reed. And in the middle  
25 of the page on September 11, 2013, apparently you met again

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2 with Adrian Hall of Brandon, and a Professor Jonathan  
3 Sackier?

4 A. Yes, that was the chap that I mentioned previously.

5 Q. Okay. And you say:

6 "It's not really aerodynamics we're looking at when  
7 Bair Huggers and lights mess up laminar airflow, as the  
8 velocities are too low. It's another form of fluid  
9 dynamics that is the relevant expertise."

10 What did you mean by that?

11 A. That is someone who has done a very small -- well,  
12 done as much reading as I can on the subject, and not really  
13 grasped the full meaning of how lights and laminar flow and  
14 aerodynamics works. The physics behind airflow in these  
15 areas is extremely complicated, and that was part of the  
16 conversation that I'd had with professor Sackier and Adrian  
17 Hall. And I think I was trying to summarize the fact that  
18 airflow is not obvious. The way air flows in operating  
19 rooms is not obvious. What I meant by that is if you think  
20 of a car or an aircraft, those systems deal with fairly  
21 high-speed airflow, which is quite predictable. But when  
22 you are looking at low-speed airflow, it is much more  
23 susceptible to changes in temperature, humidity, and  
24 other -- and turbulence in the area. And so, basically,  
25 what I meant is it's very complicated and it needs further

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2 study. Yeah.

3 Q. And you also came to the conclusion that bubbles  
4 were quite a coarse measurement?

5 A. Of?

6 Q. Airflow.

7 A. They're --

8 MR. SACCHET: Objection to form.

9 A. I don't know what you mean by "coarse".

10 BY MR. C. GORDON:

11 Q. If you flip to page 772, please.

12 A. Yes.

13 Q. An E-mail from you to Mike Reed, dated May 28,  
14 2013.

15 A. Yes.

16 Q. Towards the middle of the second paragraph of your  
17 e-mail, you say:

18 "Certainly, with the particle counter,  
19 I observed occasional particle jumps for no obvious  
20 reason, in an empty theater ..."

21 A. Yes.

22 Q. "... in the middle of a laminar flow zone. We  
23 haven't seen these in these experiments, as the bubbles are  
24 quite a coarse measurement method, but it's likely they  
25 happen."

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2 A. Yeah, so --

3 Q. So what did you mean by "a coarse measurement  
4 method"?

5 A. So we're dealing with microscopic particles,  
6 particles that are too small for the naked eye to see. And  
7 what bubbles do is show flow, but they don't show particles.  
8 And the way -- given that we're actually looking at -- what  
9 we're interested in is particles, I would describe particle  
10 counter as something which has a little more precision in  
11 terms of the sizes of particles that are drawn into its  
12 field. The good thing about using bubbles is that they can  
13 be seen. They can be visualized, and you can actually  
14 visualize airflows in the room, because there aren't many  
15 methods which will accurately do that. Using smoke has its  
16 own problems, using dry ice has problems. And so these are  
17 probably the most accurate way to measure low-speed air flow  
18 in this area.

19 But what I mean by "coarse" is that they're not the  
20 be all and end all. I think this sort of investigation  
21 really needs to use several methods in tandem, or  
22 working together to try to drive forward understanding  
23 of the area. I think bubbles is one, and I think it's  
24 very valid, but I think particle measuring is valid and  
25 useful, I think bacterial sampling is useful, I think

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2 statistical data from real operations is useful.

3 A randomized control trial would be the very best. But  
4 it's data which is useful, but does not give us the  
5 whole story.

6 Q. And even particles are a surrogate for what may or  
7 may not be bacteria?

8 A. Particles are a surrogate for what may or may not  
9 be bacteria, and also, different particle sizes have very  
10 different flow characteristics. There is -- there is a  
11 concept of a particle in terms of its diameter, its physical  
12 size, but there's also the aerodynamic diameter of  
13 a particle. So a particle can behave as though it is  
14 a smaller or larger particle, depending on its density or  
15 depending on the way it interacts with the environment  
16 around it. So the physical size of a particle may not be  
17 the same as the aerodynamic size, which may affect its  
18 settling rate, it may affect its deposition rate, it may  
19 affect its likelihood to be blown off course by a gust of  
20 wind or a gust of heat.

21 And so these are -- the bubbles show airflow; they  
22 don't show particles. They show where air currents are  
23 moving throughout the room, and because particles are  
24 very light, we extrapolate that data to give us an idea  
25 of where particles are likely to be flowing. But this

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2 is still a probability exercise. We can't say that  
3 a particle that starts here -- sorry, that a bubble that  
4 starts here and ends here, will a hundred percent be  
5 tracked by a skin flake or a piece of dust that starts  
6 there and ends there.

7 Q. If you flip back to page 610, in your September 11  
8 e-mail of 2013 to Mr. Reed. This again, apparently, is to  
9 do with whatever you were talking about with the Brandon  
10 group. You say:

11 "The target has to be equating our particle  
12 transfers to actual colony forming units to drive the  
13 message home."

14 Did I read that correctly?

15 A. Yes.

16 Q. What did you mean by "equating particle transfers  
17 to the actual colony forming units"?

18 A. So the advantage, the reason that I was speaking to  
19 this company, was because I wanted to try to do experiments  
20 in an experimental operating room. There are techniques  
21 that you can use where you put non-harmful bacteria in the  
22 air, but you spray them around and see where they settle.  
23 You can't do that, obviously, in a real operating room  
24 because there's a risk of infection to patients. So if you  
25 have an experimental operating room that's built to the same

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2 specifications as a real operating room, then you can design  
3 experiments which let us investigate this more closely. And  
4 what I wanted to do with this line of investigation was  
5 a more advanced, sophisticated version of the very first  
6 experiment, which is to see if -- you know, if I put  
7 particles on my skin, say, and rub my hands together, or do  
8 something which disrupts particles or creates particles in  
9 the room, and I know they are tagged with harmless bacteria,  
10 if I can show where bacteria go and correlate those with  
11 where air is flowing, that would be a very -- that would be  
12 an important step in understanding how particles move  
13 through an operating room and how particles may settle in  
14 a patient or in a wound.

15 Q. What came of the Brandon stuff?

16 A. It didn't go anywhere.

17 Q. Why?

18 A. I think -- I can't quite remember. I think Brandon  
19 was keen. I was keen. I think I was -- they hadn't built  
20 this experimental operating room. Brandon's interest was  
21 that they had designed operating lights which were -- I use  
22 the word "aerodynamic" carefully, but aerodynamic, which  
23 presented a lower interference area to laminar flow than  
24 other lights. And what I was interested in doing was trying  
25 to develop lights which would not disrupt laminar flow at



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2 all. And I think they were interested in looking at that  
3 because, from a marketing point of view, if a company can  
4 demonstrate that its lights don't disrupt laminar flow, that  
5 would be a good marketing thing. So I figured we had some  
6 aligned interests in demonstrating how to reduce infection;  
7 and if I could be involved in developing lighting systems  
8 which were safer, then that's -- that was why I was  
9 interested.

10 But as far as I'm aware, the experimental operating  
11 theater hasn't been built. If it has, then they haven't  
12 told me about it. And we couldn't really proceed  
13 without that experimental facility being available.

14 Q. So the absence of the facility is what stopped this  
15 from going any further?

16 A. Yeah, I think so. I think that -- I mean, I can't  
17 remember the exact chain of events, but it's one of those,  
18 the oft repeated story of starting a project and then having  
19 an idea and then letting it fall by the wayside because it  
20 just doesn't go anywhere. Had I stayed in orthopedics, this  
21 would very likely be the sort of thing that I would be  
22 chasing up probably about now, because there is long lead  
23 time to such things. But in 2013 I had just started working  
24 as a teaching fellow at a university, and so I was still --  
25 I still am doing some of this research in this area, but I

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2 had other priorities, and so they took over from this sort  
3 of research. These things come in peaks and troughs.

4 Q. Flip back to 772, if you would. That's your  
5 May 28, 2013, e-mail.

6 A. 772?

7 Q. 772, yes.

8 A. Yes.

9 Q. Correct me if I'm wrong, but I believe you're still  
10 talking about the Brandon research?

11 A. No, this may be -- there was no research -- no,  
12 right. There was no research going on with Brandon.  
13 Brandon was just speculative in scoping, and we wanted to do  
14 something and we never did it. This was research done at  
15 Wansbeck Hospital in an operating room, another experimental  
16 set-up with a mannequin, but this looked at the influence  
17 that lights have on laminar flow. So this, as far as  
18 I remember, does not have any -- anything to do with  
19 Bair Huggers or HotDogs, or anything like that. This purely  
20 looks at the influence that operating lights have on laminar  
21 flow and uses bubbles to visualize airflows and see if  
22 laminar flow is able to clear bubbles if operating lights  
23 are in the way. And what we found is that it doesn't. The  
24 laminar flow has an effect on operating lights.

25 Q. Okay, if you back up to 770, there's a May 23

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2 e-mail where you make reference to Adrian Hall at Brandon?

3 A. Yes.

4 Q. But so -- but what you're talking about on May 28  
5 is unrelated to that?

6 A. May 28? Hang on. 28th, where is the 28th?

7 Q. 772.

8 A. Oh yeah. I think this is the -- yeah, this is an  
9 e-mail chain discussing that experimental study in Wansbeck  
10 which looked at the influence that lights have on laminar  
11 flow.

12 Q. And one of the reasons for doing that study, you've  
13 described to Mr. Reed, was to build an understanding of how  
14 laminar flow works?

15 A. Yeah.

16 Q. You go on to say that:

17 "It's clear that no-one really has a clue  
18 what's going on beyond the diagrams they remember from  
19 FRCS prep, and these experiments help us get some small  
20 insight into airflows in these systems."

21 Did I read that correctly?

22 A. Yeah. What I meant by that is most surgeons.

23 Q. FRCS is Fellow of the Royal College of Surgeons?

24 A. Yes.

25 Q. So what kind of a prep are you referring to there?

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2 A. Prep ... err, yeah. What I mean is when you're  
3 studying for exams, you have some books which show operating  
4 rooms. When you do surgical exams, there are things that  
5 you should know. There are just bits of trivia which aren't  
6 particularly relevant to how you practice medicine, but  
7 there are things that it's generally accepted that one  
8 should know. For example, the number of changes of air per  
9 hour in an operating room, and some very basic principles of  
10 how laminar flow works. And I think what I was referring to  
11 there is the -- is a diagram -- I have an image in my head  
12 of a diagram of a side view of a laminar flow operating  
13 theater showing a laminar flow unit in the ceiling and  
14 columns of air moving down at exactly the same rate, which  
15 is inaccurate. That's not what laminar flow looks like.  
16 But it's just a diagram, and it's a model that people have  
17 in their heads which is not -- it's not -- I mean it's based  
18 in reality, but it is not accurate. It is a model.

19 And so I think what I was saying there is that this  
20 is very complex, and it is simplified, and rightly so.  
21 There is no reason for most people to understand it in  
22 any detail, but the more we investigate it, the more we  
23 find out about how very complex it is, and how very  
24 fragile laminar flow is, and how easily it can be  
25 disrupted and how what we assume to be the protected

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2 benefits of laminar flow require more investigation.

3 Q. There are lots of things that can disrupt laminar  
4 flow; right?

5 A. There are many things that can disrupt laminar  
6 flow; I agree.

7 Q. And in a typical surgery, whether there is  
8 a Bair Hugger, or HotDog, or no warming at all, there are  
9 lots of different things that disrupt laminar flow?

10 A. There are lots of other things in addition to any  
11 sort of warming device, whether it is used or not, and what  
12 technology. There are many factors which affect laminar  
13 flow.

14 THE COURT REPORTER: Could we have a break soon?  
15 Is that okay?

16 MR. C. GORDON: Yes, let's have a break.

17 THE VIDEOGRAPHER: This is the end of DVD 3 in  
18 volume 1 in the deposition of Dr. McGovern. Going off the  
19 record at 20 past 4.

20 (4:20 p.m.)

21 (Break taken.)

22 (4:29 p.m.)

23 THE VIDEOGRAPHER: This is the beginning of DVD 4  
24 in volume 1 of the deposition of Dr. Paul McGovern. We're  
25 back on the record at half past four.

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2 BY MR. C. GORDON:

3 Q. If I could have you turn to page 767. It's an  
4 e-mail from you to Mark Albrecht, dated October 19, 2011.  
5 Apparently you had just started at the Medway Trust?

6 A. Yes.

7 Q. You say:

8 "I'm going to do a little 'real world' study,  
9 just thought you guys might be interested to see. If  
10 you can think of any other data we should be  
11 collecting, let me know."

12 What does that refer to?

13 A. That remembers to the one or more audits that I was  
14 attempting to do at Medway, in which I noted that they were  
15 using both Bair Huggers and HotDogs, and that this  
16 correlated with the research that I'd done previously, and  
17 that I was letting Mark Albrecht know that I was considering  
18 doing that, or trying to do that.

19 Q. But other than what we've talked about, nothing was  
20 actually done at Medway?

21 A. I mean, I made a lot of effort to try and do things  
22 at Medway, but nothing ended up being outputted from Medway  
23 which was completed. So, as we've discussed previously,  
24 I've produced draft, I've produced proposals, and -- for at  
25 least two things. One of them was temperatures in operating

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2 rooms and one of them was, I think, patient temperatures pre  
3 and post-operation. But nothing -- yeah, nothing was --  
4 nothing came of that in the end.

5 Q. If I could have you turn to, and now in volume 1A,  
6 to page 80. This is an e-mail from Mike Reed to Mark  
7 Albrecht with a copy to you and Scott Augustine. It says:

8 "Mark. This is a great paper. I have made  
9 some comments.

10 "I know we will be going over the data  
11 tomorrow. My concern here is that we couldn't  
12 replicate this effect in our own OR. I wonder if you  
13 would consider setting the experiment up again and  
14 simply demonstrating the effect to Paul and I via  
15 Skype. Not suggesting at all that it is repeated but  
16 that we can simply see the bubbles rising into the  
17 surgical site with this set up, and that we can see the  
18 particle counts measured so high in the surgical field.  
19 We could use that video in our blog anyway. Sound  
20 plausible? If we are publishing/speaking on this we  
21 need to have witnessed the phenomenon in our own OR  
22 didn't show that effect (although the air bubbles did  
23 rise to some extent with us)."

24 Did I read that correctly?

25 A. Yes.

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2 Q. What effect were you and Mr. Reed not able to  
3 replicate in your own OR?

4 A. I don't know, because I don't know what the paper  
5 which is referred to contains. So I'd need to look through  
6 that paper to know what -- or to have idea of what Mike Reed  
7 is referring to.

8 Q. Can you tell, from this e-mail, what the -- what  
9 paper we should be looking for?

10 A. The filename is Manuscript\_Laminar\_7-9(2).doc. But  
11 I don't know what paper this is.

12 Q. Well, the Manuscript\_Laminar\_7-9, that's something  
13 we should be able to find in the index? I mean, that's  
14 something --

15 A. I imagine so. I mean it's -- I've done my best to  
16 include every file that was attached. It's likely to be  
17 there.

18 Q. Let me just say, by the way, I love the way your  
19 attorneys produce documents with an index. This is  
20 wonderful. It looks like it should be in volume 5, which is  
21 exhibit 7A. Apparently one of the first documents.

22 A. Volume 5, 7A. Ah, it is.

23 Q. Is that it?

24 A. This version 1, so --

25 Q. According to the index, version 2 comes next.



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2 A. It does. That looks like the right one. Okay. So  
3 your question was?

4 Q. Well, let's first take a look at what this document  
5 is. So in exhibit 7A, this begins on page 2012 and goes  
6 through 2036; is that right?

7 A. Yes.

8 Q. And the title on this draft, at least, is "Forced  
9 Air Warming Versus Conductive Fabric Warming -- An  
10 Evaluation of Laminar Operating Room Ventilation  
11 Disruption"?

12 A. Yes.

13 Q. And it lists as authors: Reed, McGovern, Gauthier,  
14 Albrecht and Nachtsheim?

15 A. Yeah.

16 Q. Was this something that was published?

17 A. I can't remember.

18 Q. Looking at the method section on page 2017, it  
19 refers to: "A laminar flow OR environment was constructed  
20 for this experiment ..."

21 A. Yes.

22 Q. "... because most hospitals will not allow the use  
23 of tracer smoke or permit an open flame in the OR."

24 A. Yeah.

25 Q. Were you involved in any experiment in a specially

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2 constructed laminar flow environment?

3 A. I was not.

4 Q. Are you aware of any that were done that you  
5 weren't -- that you weren't physically --

6 A. Yeah, I was aware that Augustine, the company, had  
7 a laminar flow environment -- a lab -- and that they did  
8 experiments in that place.

9 Q. Is that what this refers to, this document --

10 A. I don't know.

11 Q. -- that begins on 2014?

12 A. I -- yeah, I don't know.

13 Q. So, does this help you interpret or explain what  
14 effect you couldn't replicate in your own OR?

15 A. It does not, because I don't know what Mike Reed is  
16 referring to in this e-mail.

17 Q. Okay. Do you recall a video being sent to you  
18 showing anything that was -- any activity that was being  
19 done in the mock OR?

20 A. So the video that was referenced previously, which  
21 was sent to lots of orthopedic surgeons in the U.K., is one  
22 which I think was filmed in an experimental environment  
23 which involved traces of smoke and light, and lighting to  
24 visualize airflows. But I do not know if this refers  
25 specifically to that video or that place, or that set-up.

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2 They all seem similar, but I don't know if they are one and  
3 the same.

4 Q. Okay. This was -- page 80 was July 18, 2010.

5 A. Yes.

6 Q. If I could have you turn now to page 201.

7 A. Shall I keep this one open?

8 Q. I don't know that you need to.

9 A. We'll get back to it. So say the page number  
10 again?

11 Q. 201.

12 A. Yes.

13 Q. And this is an e-mail from Mark Albrecht to  
14 Mr. Reed and yourself, cc'd to a few people. It is dated  
15 August 20, 2010. And Mr. Albrecht says:

16 "Mike and Paul,

17 "I'm trying as best I can to get that helium  
18 bubble generator back into the States here, but it is  
19 still caught up in customs."

20 Talks about that for a little bit, and then  
21 he says:

22 "I fear that our ability to get this  
23 completed manuscript in (see attached) will continue to  
24 be delayed for some time if we rely upon that equipment  
25 to demonstrate the effects for both of you in our

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2 laboratory."

3 And the title on this is "Laminar Flow  
4 Manuscript".

5 He then goes on to say:

6 "I'm hoping we can take a different approach  
7 here. OK, both Chris Nachtsheim (faculty at the  
8 University of Minnesota) and Bob Gauthier (independent  
9 anesthesiologist) have seen the effects first hand  
10 shown in the photographs (Figure 6 in the manuscript)."

11 Maybe it would be helpful to have the  
12 manuscript. If you go to page 2033, go to Figure 6.

13 A. Hang on, do you mean -- I think you mean a  
14 different one. This is 819, and so that should be 20 ... do  
15 you mean 2053 or 54?

16 Q. Say again?

17 A. Do you mean 2053 or 54? Because you're looking at  
18 the previous version, and this is referring to Manuscript  
19 Laminar 8-13, this e-mail, that's the attached one.

20 Q. Oh, so it's a later version?

21 A. Yes.

22 Q. I think Figure 6, then, would be page 2058.

23 A. Yes, 2058.

24 Q. Okay. So Albrecht goes on to say:

25 "Bob is more than happy to assume the lead

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2 authorship role and verify the fidelity of our research  
3 (he has seen it first hand)."

4 Do you recall -- and I recognize this six and  
5 a half years ago, but do you recall that you were being  
6 asked to sign off on something based on representations  
7 of others who had actually seen the effect that you  
8 weren't able to replicate yourself?

9 A. I don't recall that.

10 Q. If you turn to the next page, 202, there's an  
11 e-mail that appears to be from Robert Gauthier to Albrecht  
12 and Reed, and you. And basically he's saying he has seen  
13 this effect many times?

14 A. Yes, yes.

15 Q. And do you recall seeing this e-mail ever?

16 A. I don't recall it, but I -- well, I did see it  
17 because I replied to it. But I don't recall it.

18 Q. When you replied to it, were you aware that Mark  
19 Albrecht had drafted the e-mail that appears over Bob  
20 Gauthier's signature?

21 MR. SACCHET: Objection to form.

22 A. Was I aware that Mark Albrecht had written the  
23 e-mail that -- what, the e-mail on -- dated 20th August?

24 BY MR. C. GORDON:

25 Q. 20 August 2010, at 19:23.

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2 A. Was I aware that Mark Albrecht had written that  
3 e-mail?

4 Q. Yes.

5 A. I'm not aware now. I can't imagine why I would  
6 have been then.

7 Q. Okay. Do you know what happened subsequent to the  
8 exchange e-mails in terms of the laminar flow manuscript?

9 A. I don't remember what happened to this project, if  
10 anything.

11 Q. Do you recall there being a decision not to try and  
12 get the laminar flow manuscript published?

13 MR. SACCHET: Objection to form.

14 A. I don't recall if -- what happened with this  
15 document we're referring to after this point.

16 BY MR. C. GORDON:

17 Q. And as you sit here, you don't recall anything like  
18 you and Mr. Reed saying, you know, "Since we haven't been  
19 able to replicate this ourselves, and haven't actually seen  
20 it, we'd just as soon not be part of this"?

21 MR. SACCHET: Object to form.

22 A. I don't recall that conversation. The e-mail that  
23 I've written back is very much palming off the question.  
24 We're being asked to comment on it, and I have said I'm not  
25 commenting on it until Mike comments on it. And I don't

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2 have any other information as to what Mike Reed said after  
3 that, but I don't recall any conversations about this.

4 BY MR. C. GORDON:

5 Q. Okay. If I could now have you turn to 241. An  
6 e-mail from Scott Augustine to several people, including  
7 you, dated September 23, 2010.

8 A. Yes.

9 Q. And this concerns an interview that Augustine had  
10 with the New York Times. Do you recall receiving this  
11 e-mail?

12 A. Yeah, I received this e-mail, and I don't remember  
13 the first time I saw it, but I did receive this e-mail.

14 Q. Were you contacted by a reporter from the New York  
15 Times?

16 A. No, I wasn't contacted by anyone from the New York  
17 Times.

18 Q. Prior to receiving this e-mail, did you know who  
19 Randy Benham was?

20 A. I don't think I did. I don't -- oh, in 2010?  
21 I think he is, or was, a lawyer working for Augustine, but  
22 I'm not 100 percent sure on that. I don't know if I knew  
23 who he was before this point.

24 Q. I've just realized your lawyer has stepped out. In  
25 fairness, I want to hold off until he comes back.

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2 THE VIDEOGRAPHER: Go off the record?

3 MR. C. GORDON: I don't know.

4 MR. SACCHET: He's coming in.

5 THE VIDEOGRAPHER: Deposition is being rejoined by  
6 Andrew Head.

7 MR. HEAD: Hello again.

8 MR. C. GORDON: Oh, goodness, we don't want to be  
9 headless. Thank you.

10 MR. HEAD: (inaudible)

11 MR. C. GORDON: I'm sure that's the very first  
12 time you've ever heard that comment.

13 MR. HEAD: Two heads are better than one.

14 MR. C. GORDON: I'm sorry, I noticed your absence  
15 so we kind of altered things. What was the last question  
16 and answer?

17 (Record read.)

18 BY MR. C. GORDON:

19 Q. Have you ever met Randy Benham?

20 A. I think so. I couldn't put a name to the face, but  
21 when I was in the States doing the research at the  
22 University of Minnesota, I think I met him. But I don't  
23 remember clearly.

24 Q. Have you had any communications with Mr. Benham  
25 subsequent to meeting him in Minnesota?



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2 A. Subsequent to -- um, I don't think so. It's  
3 certainly possible that he's been copied in on other  
4 e-mails, because that's not something I would have noted on  
5 lots of e-mails. I don't remember having a conversation  
6 with him. If I have, it's short and brief. I don't --  
7 I haven't been in significant contact with him, to my  
8 recollection, no.

9 Q. Have you had any communication with any of the  
10 lawyers representing the claimants in the United States?

11 A. The claimants? I got an e-mail on LinkedIn from  
12 someone, but I think they were for -- they were representing  
13 3M, from my memory. No, I haven't had any e-mails from  
14 lawyers representing the claimants, to my knowledge.

15 Q. Have you had any -- no phone calls?

16 A. No.

17 Q. No face-to-face meetings?

18 A. No.

19 Q. Okay. If you turn to 426, please. It is a May 31,  
20 2010, chain of e-mails between you and Mr. Reed.

21 A. Yes.

22 Q. Subject is the "AAOS draft". Do you know what that  
23 is, off the top of your head?

24 A. Yeah, this was the submission for the initial study  
25 that we talked about, the experimental study which involved

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2 plate sampling for bacteria and particle counting. This  
3 relates to the abstract submission to the American Academy  
4 of Orthopedic -- or American Association or Academy of  
5 Orthopedic Surgeons -- to try and get this research  
6 presented at a peer-reviewed meeting.

7 Q. And if you look at the bottom of page 426, you  
8 write to Mr. Reed:

9 "... funding wise we have nothing to declare  
10 from this one?"

11 A. Yes.

12 Q. Right. If you turn to the next page, Mr. Reed  
13 replies: "Yes, Augustine Biomedical."

14 A. Yes.

15 Q. What was your understanding of Augustine  
16 Biomedical's funding, or what was your understanding of why  
17 you -- why Mr. Reed thought you needed to declare that  
18 Augustine Biomedical?

19 MR. SACCHET: Object to form.

20 A. I don't know what my understanding of that was at  
21 the time. I asked the question of Mike Reed because I had  
22 been asked the question by the AAOS, and I wanted to make  
23 sure my declaration was correct, and the answer was provided  
24 for me by Mr. Reed.

25 BY MR. C. GORDON:

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2 Q. If I could have you turn to page 150 in volume 1 of  
3 your documents, so that's exhibit 3A.

4 A. Sorry, volume which?

5 Q. It's exhibit 3A, or volume 1 of your documents.

6 A. Which page, sorry?

7 Q. 150.

8 A. Yes.

9 Q. Just tell us what that is.

10 A. This is the -- this is an abstract submission,  
11 whether it is a draft or the final, I don't know, to the  
12 British Hip Society for the bacterial sampling and particle  
13 sampling study that we were talking about initially.

14 Q. What -- do you recall whether you did submit this  
15 to the British Hip Society?

16 A. I don't recall whether -- this meeting, there was  
17 more than one submission. I presented one podium  
18 presentation and at least one poster. I believe that this  
19 was submitted, but I don't remember if this was submitted.

20 Q. Do you recall submitting the presentation on the  
21 bacterial study to more than one group?

22 A. I don't recall doing that. It's quite likely that  
23 I did, because that is -- I would -- if I've produced an  
24 abstract for one meeting, then that work to produce an  
25 abstract is effectively done, and so it is a very low amount

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2 of work to submit something to another meeting in the hope  
3 that it gets accepted. But I don't remember whether  
4 I submitted that study to more than one meeting.

5 Q. The -- is it the AAOS one, or the -- or you know  
6 you submitted it, and they rejected it?

7 A. Yes, because we've already looked at the AAOS  
8 rejection e-mail earlier today.

9 Q. Would you, if you had submitted it to BHS and they  
10 had sent you a rejection e-mail, would you expect that to be  
11 in the materials that you produced?

12 A. It may be. I can't remember. The thing is,  
13 because I know that I got an acceptance e-mail from BHS, it  
14 may be included in the acceptance e-mail, or it may not have  
15 come through at the same time. Because if you get two  
16 e-mails from an auto-send, it may have gone to spam or  
17 something. I just don't know if that's that rejection  
18 e-mail, or the confirmation that I sent it is included in  
19 this, because I don't remember if I submitted it.

20 Q. If you would turn to page 445 in exhibit 1A,  
21 volume 1 of the e-mails.

22 A. 445?

23 Q. Correct.

24 A. Yes.

25 Q. And looking at the chain of e-mails and trying to

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2 translate the dates from American to British, and vice  
3 versa, it looks like this goes from -- it's a long one. Am  
4 I right that this -- oh, no.

5 A. 452?

6 Q. Yeah, so 452 is the beginning of it. And this is  
7 a series of e-mails that start discussing the bacteria study  
8 that had been completed; is that right?

9 A. Well, Valerie Edwards-Jones is included, which  
10 suggests that it is that study. But I don't know if this is  
11 related to the study that was already done, or discussion of  
12 a future study which -- it doesn't look like it's discussing  
13 particularly the bacterial sampling study. It looks like it  
14 may be discussing a possible further study.

15 Q. The only reason I am wondering if it was after this  
16 study was on page 452, there is a line from Mr. Reed that  
17 says:

18 "There is also the issue of where the hot air  
19 goes from the forced air, but I appreciate we didn't  
20 find bugs/particles in the field."

21 A. Yes.

22 Q. Would there have been some other experiment or  
23 study that you did?

24 A. Not that I know of. I think this is -- it's  
25 difficult to be absolutely sure what this refers to, but it

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2 looks to me as though this is referring to -- or this is  
3 a discussion about a potential future study and is  
4 referencing the past study that we've already discussed  
5 involving bacterial sampling, which didn't show bugs in the  
6 field. Although that's inaccurate, because we couldn't test  
7 for bugs in the field, only in the vicinity of the field.

8 Q. And on further research, if you look to page 446,  
9 there's a fairly long e-mail from Augustine to Reed, Leaper,  
10 Robin Humble, cc'd to Val Jones, Laura Ludman, Keith Leland,  
11 Mark, Randy Benham?

12 A. Yes.

13 Q. And I guess you ended up with it as part of  
14 a chain?

15 A. Yeah, it looks like it, because it wasn't sent to  
16 me.

17 Q. Augustine says:

18 "My suggestion for further research would be  
19 to start by basically replicating and thus verifying  
20 the research that we have done in our lab. Maybe not  
21 too exciting but practical and very useful.

22 "1.) Use tracer smoke under the table and  
23 particle counting above the table (after-hours with a  
24 mannequin instead of a patient), both in a laminar flow  
25 and non-laminar flow OR.

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2 "2.) In the UK laminar flow lab, replicate  
3 the DVD with smoke and laser lights."

4 Augustine goes on to say:

5 "I like this plan because we know the  
6 outcomes before we do the studies and yet they are  
7 scientifically and clinically important questions that  
8 need verification in multiple studies. I should  
9 mention that we repeated the experiment of tracer smoke  
10 under the table and particle counting over the wound  
11 with BH on high and one person standing next to the  
12 table pretending to be a surgeon. This time we  
13 measured 61% of the particles ending up over the wound  
14 compared to the concentration under the table! We had  
15 a hose-end filter on the BH, so none of the particles  
16 were being emitted from the blower and all represented  
17 simply the 'dirty air near the floor' being picked up  
18 by the waste heat and carried into the wound. The  
19 particles in the background laminar flow were  
20 essentially zero. Stunning!

21 "I personally am not too excited about  
22 culturing the wound at the end of the case, either  
23 directly or by irrigation. Without having done a pilot  
24 study, this is a 'crap shoot' that could go either way.  
25 I think it is important to consider that even if this

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2 type of study were to turn out positive, it could be  
3 considered to simply be another intermediate step  
4 similar to particle detection over the wound. In other  
5 words it does not conclusively answer the question of  
6 'does FAW cause wound infections?' Therefore, I'm not  
7 sure that it really adds enough to our case to take the  
8 risk of a negative study."

9 Did I read that all correctly?

10 A. Yes.

11 Q. Do you recall reading this back in 2010?

12 A. I do not.

13 Q. Is your approach to doing tests to try to know the  
14 outcome before you do the studies?

15 A. No.

16 Q. I see.

17 A. Although, in practice, the whole point is to have  
18 a null hypothesis, so you are testing an outcome. You may  
19 have idea of what the outcome might be, but the whole point  
20 of scientific investigation is to have an idea and then to  
21 test whether you are right or wrong. So I would not -- I  
22 wouldn't say I would know what the outcome is of any test,  
23 otherwise there's no point doing it. But you may have an  
24 idea, because you may be testing something that you've  
25 observed clinically, and then are trying to get that



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2 statistically proven.

3 Q. Okay. And is it -- in your approach to research,  
4 you balance the risk of getting a negative study if you  
5 haven't done some sort of a pilot study?

6 A. It's not -- no. The term "risk of a negative  
7 study" is not one which I would use because, to me, there  
8 isn't a risk in itself of having a negative study. It's not  
9 something that I'd see as a negative thing. Having said  
10 that, negative studies are -- it's well recognized --  
11 published less frequently than studies with positive  
12 findings, which is really a flaw of the peer-review process  
13 and of research in general. But, as a researcher, if I were  
14 testing something important which were up for debate, and  
15 I were to find something negative, I would try to publish  
16 it.

17 Q. In his reply to Augustine, which he shared with  
18 you -- or did he? At what point were you brought into this  
19 back and forth?

20 A. I don't -- it doesn't look like I was brought into  
21 it until Mike sent me an e-mail asking me to send my latest  
22 version, but I don't know what that latest version is of.

23 Q. Okay.

24 A. I suspect that, as we've seen, some -- the paper  
25 had been sent to me, and I had -- I don't know if this is

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2 before or after this -- said "I want to wait to see what  
3 Mike Reed says," but I hadn't commented on it. I had not  
4 marked up the document or edited it. So it may be that Mike  
5 Reed meant that. But I wasn't involved in this  
6 conversation. I don't remember reading any of this.

7 Q. And the title, "Turbulent flow from the hot  
8 dinosaur," do you know what that means?

9 A. I don't know what it means. I could speculate.

10 Q. Okay. Well, going back to page 445, in response to  
11 Augustine's proposals for further research, Mr. Reed says:

12 "Scott -- I am fully with you -- the combined  
13 effect is what matters clinically. As a surgeon I am  
14 unconcerned (although I am interested) as to whether  
15 the disruption is caused by one or both methods.

16 "I agree the DVD is compelling but there is  
17 no data to get it into a meeting or a journal. What is  
18 needed is data to write abstracts for meetings and  
19 papers -- that way the DVD will get an audience."

20 Did you have any discussion with Mr. Reed  
21 about trying to generate an audience for the Augustine  
22 DVD?

23 A. No, not to my recollection.

24 Q. Continuing on to page 446, Mr. Reed says:

25 "All that said I am keen to re-do/verify the

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2 smoke studies as per your plan 1 and 2. 61% of  
3 particles is very compelling -- I guess my only concern  
4 with pushing this is that when we did this on a patient  
5 model in a real OR there were actually no particles --  
6 so I guess 61% of that doesn't sound much."

7 A. Yes.

8 Q. Do you know what he was referring to there? Is  
9 that the study that -- the microbiology study?

10 A. Yeah. The difference with that is that, from my  
11 understanding of reading this e-mail just now, 61 percent  
12 refers to particles that are introduced into an area, so  
13 there are lots of particles around. It seems to be  
14 referring to movement of particles which have been  
15 introduced, whereas the study we were talking about  
16 previously looks at particles which weren't there in the  
17 first place, or may not have been there in the first place.  
18 So they're very different.

19 Q. So was your -- did you have any discussions about  
20 trying to do airflow visualization studies with smoke?

21 A. When I was initially looking at this whole area,  
22 when Mike Reed asked me to come up with the design of  
23 a study which turned into the bacterial -- bacterial  
24 sampling study we've been looking at which wasn't published,  
25 at some point, either during, before or after that, I tried

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2 to work out how to visualize airflows. And I did hire  
3 a dry-ice machine used in theaters to try to visualize how  
4 air flowed around the room. But that didn't work because  
5 dry ice sinks and cools. So I attempted to use that method  
6 to see how air was flowing, but it was ultimately a failure.  
7 So it was not even a study; it was just playing around in an  
8 operating theater which wasn't in use.

9 I have also, at some point, used not just  
10 a dry-ice smoke machine but a theatrical fogging  
11 machine, which uses, I think, very fine oil mist heated  
12 up which suspends particles in the air, and attempted  
13 to use that to visualize laminar air flow. But it  
14 wasn't particularly effective.

15 Q. When was this, in relation to when you did the  
16 bubble study?

17 A. I can't absolutely remember, but I think the dry  
18 ice -- well, it wasn't an experiment, but the experimenting  
19 with dry ice was -- previously, that was a separate idea  
20 which I did, I think just myself and Mike Reed, because the  
21 dry ice expires. It boils off, so you have to do it  
22 quickly. And I think the fogging with the theatrical  
23 material was done when Mark Albrecht was in Wansbeck. It  
24 may have been done at other times as well, but I can't  
25 remember exactly the time. I think around the time of the

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2 bubble study.

3 Q. Tell me again, does something like Rocket PS2 sound  
4 familiar?

5 A. No.

6 Q. For a machine?

7 A. It might be the fogging machine, but I can't  
8 remember.

9 Q. Okay. In any event, this fogging machine, that was  
10 something that Mark Albrecht brought to Wansbeck?

11 A. I guess so. I don't know. I did hire some  
12 equipment to try and play around with visualizing airflow.  
13 I don't think I hired that. Or I might have done; I don't  
14 remember.

15 Q. So who actually tried it out? Just you and Mark?

16 A. I don't think I was ever there with Mark on my own,  
17 from memory, but yeah, I think we just set the smoke off in  
18 a controlled way to see what would happen.

19 Q. In a laminar flow room?

20 A. Yeah.

21 Q. And what happened?

22 A. I think the laminar flow cleared the smoke away.  
23 This is without an operating table in the area, as  
24 I remember. The problem with that was it was going to set  
25 the fire alarms off, so we very quickly gave up on that idea

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2 because we didn't want to cause disruption to the work in  
3 the hospital. It was at the weekend and the hospital was --  
4 the operating room was due for a deep clean anyway, so  
5 that's why we had equipment in there. But we saw the amount  
6 of smoke that this thing could produce, and thought we  
7 didn't really want to risk setting the fire alarms off and  
8 calling the fire service out, and so we sort of abandoned  
9 that.

10 Q. Because the laminar flow was sufficient to clear  
11 the room?

12 A. It was so -- it was such a short lived thing, as  
13 far as I remember, that we didn't really get an opportunity  
14 to properly use smoke in a real operating room to visualize  
15 laminar flow, because it became apparent fairly quickly that  
16 as laminar flow was clearing the smoke, it was going into  
17 external vents which would have risen outside the operating  
18 room into the corridors and caused problems. So we started  
19 it up, and very quickly just gave up on it.

20 Q. And whose idea was it, then, to explore the  
21 possibility using a neutral buoyancy bubble generator?

22 A. Well, I don't remember whose idea it was, but my  
23 understanding now is that machine belongs to Augustine's  
24 company. I didn't know, as far as I recall, where the  
25 machine originated from at the time. I knew at some point

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2 throughout the research that it had been sent over by  
3 Augustine, or Augustine's company, because of the discussion  
4 we've already mentioned about it getting back through  
5 Customs and such. But I don't remember who suggested helium  
6 bubbles. I don't remember if Mike Reed suggested it, and  
7 the machine was available, or if it was suggested by  
8 Augustine or by Mark Albrecht. I don't know who suggested  
9 it.

10 Q. The first time you were involved in it being used,  
11 did you do something similar to what you did with the smoke  
12 machine? In other words just go into an OR and see what the  
13 laminar flow did with it?

14 A. Absolutely. So the first -- with any of this  
15 equipment, with the particle counter, with the bubble  
16 generator, it's quite a temperamental piece of equipment.  
17 They're all temperamental pieces of equipment, and you spend  
18 a while getting the thing to work, and then understanding  
19 how it works, and then understanding how it -- how air flows  
20 around the room. And so, actually, some of the first videos  
21 on my blog were not of experiments, as such; they were of  
22 those scoping exercises where we would put the bubble outlet  
23 underneath a light, say, under the laminar flow and then  
24 move the light away and show the disruption that the light  
25 was having on laminar flow.

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2 So there was quite a lot of experimenting with --  
3 to better understand how air was flowing in the room,  
4 because it's -- well, it's interesting. It was  
5 something which people who were in the hospital at the  
6 time would come in and look at, and find very -- well,  
7 find fascinating, because airflow isn't something that  
8 most people think about. Surgeons think about it quite  
9 a lot, and to be able to see it is very interesting. So  
10 we spent quite a lot of time experimenting.

11 Q. Was the laminar flow clearing the bubbles similarly  
12 to the way it cleared the smoke?

13 A. I don't remember how the laminar flow cleared the  
14 smoke. I can't -- my memory of the smoke is really  
15 restricted to the thing turning on, and us being pretty  
16 concerned that the smoke detectors were going to go off. So  
17 I don't really remember how the smoke was dealt with by  
18 laminar flow. In terms of the bubbles, when laminar flow is  
19 unobstructed, it was extremely effective at clearing  
20 bubbles. And some of our videos demonstrate that. You can  
21 see a column of air, of clean air, clearing bubbles away  
22 very quickly, within seconds. And you can see the  
23 significant disruption that operating lights have on laminar  
24 flow very clearly with the bubble generate generator.

25 Q. Did you do any bubble studies with any other pieces



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2 of OR equipment, anesthesia machine?

3 A. Not with an anesthesia machine. We would put the  
4 outlet near to machines to see if they were warm, or if they  
5 created turbulence. Anything -- you get a flow boundary  
6 near any piece of equipment in the way of the laminar flow;  
7 so you'll get deflection of air off it, depending on where  
8 it is in the laminar flow zone, and how fast the air is  
9 moving, and the temperature. But we have since done  
10 experiments looking specifically, as I've mentioned  
11 previously, at the influence that the overhead operating  
12 lights have on laminar flow, and how the position of those  
13 lights affects clearance of bubbles, and therefore clearance  
14 of air from the region of the operative field. But that was  
15 subsequent to this.

16 Q. At some point, did you also -- would I understand  
17 that you were using the bubble machine to see if there were  
18 heat-generated convection currents emanating from other  
19 pieces of equipment?

20 A. To -- only sort of informally, where you've got  
21 this wand but it is picking bubbles out, and you sort of put  
22 it against people's faces and near their -- over the top of  
23 their heads and see how air flows over surgeons. It is  
24 quite interesting to see what airflow -- how airflow changes  
25 when you move your hand through an area. We didn't really

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2 focus specifically on other machines, apart from operating  
3 lights, as far as I remember.

4 Q. So, what do you call the electrocautery device?

5 A. A diathermy.

6 Q. Diathermy. Have you ever heard it referred as to  
7 a Bovie?

8 A. No.

9 Q. I think that's a brand in the U.S.

10 A. No, we don't tend to do brands in the U.K. We're  
11 pretty resistant to it.

12 Q. You didn't try to see how turning on a diathermy  
13 machine would affect the bubbles?

14 A. The machine? No, because -- well, no, we didn't.  
15 Because to actually use the machine, you'd need some meat,  
16 and we didn't have any meat.

17 Q. Any saws or drills?

18 A. Not to my recollection.

19 Q. But you did say you ran it over by the anesthesia  
20 machine?

21 A. Yeah. I mean, anything that was there in the room,  
22 we would have put the thing near. Because you're wandering  
23 around with this hose, basically playing and seeing what's  
24 happening. So anything which was anywhere near -- because  
25 the anesthesia machine sits -- tends to sit and straddle the

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2 boundary between the laminar flow zone and not, we were  
3 interested in how -- in the drop-off, because you would  
4 expect that, outside the laminar flow boundary, bubbles  
5 would circulate and collect, but they don't. It's a rather  
6 smoother area of clearance. The laminar flow zone has an  
7 area of influence just outside the boundary, so we would  
8 have looked informally at what the anesthesia machine does,  
9 but the anesthesia machine wouldn't have been on. It  
10 wouldn't have been active. It was just sitting there.

11 Q. It is just the mass --

12 A. Yeah, it is just the mass. You know, when the  
13 operating table was there, we would move that out of  
14 position, move it into position to see what -- how air flows  
15 around it. The specifics of exactly what we saw, I don't  
16 remember.

17 Q. I take it you never tried to do an airflow  
18 visualization in a simulated OR where basically everything  
19 was happening: the circulating nurse was moving, all the  
20 equipment was on?

21 A. Not to that extent. When we were actually doing  
22 experimental runs, everything was pretty controlled. So  
23 there weren't lots of people moving around the room. There  
24 was not a lot of equipment there. There was one person in  
25 the position of the surgeon, but there was no scrub nurse or

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2 trays, or anything like that. When we were experimenting,  
3 lots of people would be milling in and out of the room, so  
4 when we were working out what would be a set-up which was  
5 worth investigating, there were lots of people there, but  
6 that's not what we collected data on, because people moving  
7 around the room is not -- is a variable that you can't  
8 control for. So we wouldn't know if a particular result was  
9 because someone had walked through the laminar flow zone at  
10 the time, or if it was controlled. So in an experimental  
11 study, it was important to keep things as consistent as  
12 possible so the results were as valid as possible.

13 Q. Did you repeat the bubble experiment in more than  
14 one of the ORs at Wansbeck?

15 A. The bubble experiment, as reported, was in one OR,  
16 as I remember. That bubble generator, I'm sure, has been in  
17 more than one room -- more than one operating room. I can  
18 think of two that I think it's been in. Ah, no -- yes. The  
19 recent study looking at lights and laminar flow was in  
20 a different operating room to the one which was published in  
21 the Journal of Bone and Joint Surgery. That was the same  
22 operating room as the settle plates microbiology study. But  
23 Wansbeck bubble study, looking at the influence of  
24 Bair Huggers and HotDogs, was only done in one operating  
25 room, as far as I can remember.

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2 Q. So the settle plate microbiology study was done in  
3 a different OR than the bubble study?

4 A. As far as I remember, yes.

5 Q. Do you remember the numbers?

6 A. What numbers?

7 Q. Of the theater suites? The operating theaters?

8 A. No.

9 Q. So you wouldn't remember which one was Theater 2?

10 A. No.

11 MR. SACCHET: Object to form.

12 MR. C. GORDON: I am at a point where I would  
13 like -- I would say let me take a break, go through my  
14 remaining stuff, and I am sure I have just a few minutes  
15 left. Are you happy to do that, or do you want to just take  
16 a break for the evening? And then I promise you, when we  
17 start tomorrow, I will have less than 30 minutes.

18 MR. HEAD: Carry on.

19 MR. SACCHET: I think it is preferable to us for  
20 you to take a look and decide what you still have to ask,  
21 and then finish for the night.

22 THE VIDEOGRAPHER: Going off the record at 5:27.

23 (5:27 p.m.)

24 (Break taken.)

25 (5:39 p.m.)

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2 THE VIDEOGRAPHER: Back on the record at 5:39.

3 BY MR. C. GORDON:

4 Q. Dr. McGovern, if you could now turn to page 978  
5 through 986. I think that's volume 3.

6 A. No.

7 Q. 4?

8 MR. SACCHET: I think it might be 2, because it's  
9 preceding --

10 MR. C. GORDON: Yeah, it's 2. Sorry.

11 MR. SACCHET: Page, sorry?

12 MR. C. GORDON: 978.

13 A. 978.

14 BY MR. C. GORDON:

15 Q. And it goes on through 986, I believe?

16 A. Okay.

17 Q. Can you tell me what this document is?

18 A. It's a document by Professor David Leaper dated  
19 August 2009, a draft document titled "Augustine Biomedical  
20 Summary of Study Proposals".

21 Q. And are these -- do these proposals come out from  
22 Professor Leaper before you did the first microbiological  
23 and particle test?

24 MR. SACCHET: Object to form, foundation.

25 A. I don't know. I don't know the -- well, this

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2 document is dated before August 2009, and so I don't  
3 remember when the studies were done, but it seems unlikely  
4 they were done before August 2009, because that's when  
5 I started at Wansbeck.

6 BY MR. C. GORDON:

7 Q. Does the summary in 3, number 3, basically describe  
8 what you ended up doing in Northumbria?

9 A. Not really. There are similarities, but it's --  
10 this mentions a slit sampler which, I've said before, is --  
11 would have been a much more effective device/apparatus to  
12 use for such an experiment than the one that we ended up  
13 using. I don't think we made any evaluation of the local  
14 ambient temperature. It's similar in the sense that there  
15 is an attempt to sample for bacteria count -- bacterial  
16 counts around the wound. It's not similar because this  
17 discusses all available forced-air warmers in sequential  
18 experiments. So there are similarities, but it's not the  
19 same study.

20 Q. And of the other study proposals, 1 through 9, you  
21 didn't participate in any doing any of them; right?

22 A. "Two-centre microbiological evaluation." That's  
23 number 1. No.

24 "Single-centre evaluation of air emerging from  
25 a forced-air former hose."

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2 No. We did direct air from a forced-air warmer  
3 hose onto a plate, but that's not really a study, that's  
4 just directing air --

5 Q. And that was part of the microbiological study --

6 A. And we did it at the same time. It wasn't really  
7 a study; it was just blowing some air onto a plate.

8 Number 4: Two-center evaluation of particle  
9 counts, and temperature and slit sampling, during an  
10 operation? No.

11 Tracking -- number 5: tracking study of  
12 bacterial isolates from surgical site infections. No.

13 Number 6: Two pilot randomized control  
14 trials? No.

15 7: powered randomized control styles above  
16 pilot studies? No.

17 8: Pilot, randomized evaluation of patients  
18 with abdominal pain? No.

19 9: Pilot, randomized evaluation of systemic  
20 warming during initial hospital admission phase? No.

21 Q. And are you aware of any of those other studies  
22 being done --

23 A. No.

24 Q. -- by anyone else?

25 A. No. Mike Reed mentioned that a randomized control



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2 trial is being done which he's not leading on, but that's  
3 the only knowledge I have of any similar study going on at  
4 the moment.

5 Q. Did he tell you who was funding that?

6 A. Excuse me?

7 Q. Did he tell you who was funding that study?

8 A. The only information I have on it is the e-mail  
9 that you've seen, so I haven't had any further information  
10 that there is no information on funding.

11 Q. Okay. Now I think if you would turn to -- so, of  
12 the nine proposals from Professor Leaper, only one was  
13 actually done, sort of?

14 A. Yeah.

15 Q. The microbiological study.

16 MR. SACCHET: Object to form.

17 A. I would say, of these nine, none were done.  
18 Something that is vaguely similar superficially to number 3  
19 was done, but it's not really the same study.

20 THE COURT REPORTER: Was there an objection there?

21 MR. SACCHET: Form, yeah.

22 BY MR. C. GORDON:

23 Q. So if you could turn to volume 6, so it is exhibit  
24 8A.

25 A. Yes.

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2 Q. If I could direct your attention to page 2836.

3 A. 2836.

4 Q. Can you tell me what this is?

5 A. This looks like a poster discussing a product  
6 called Purezone, and discussing a study with regards to  
7 Purezone.

8 Q. What's Purezone?

9 A. I think it's a pillow which intends to reduce  
10 allergies, or reduce symptoms of allergies, when sleeping.

11 Q. What's your connection to it?

12 A. I don't have any connection to it. I know that it  
13 exists, and I think Mike Reed was interested in it, or  
14 expressed an interest in it. But I don't -- I've not done  
15 any work with it. I've never -- I don't think I've ever  
16 seen one in the flesh. I don't have any connection to  
17 Purezone.

18 Q. If you turn to page 2854.

19 A. Yes.

20 Q. And what is this?

21 A. It looks like a draft paper entitled "Laminar Flow  
22 And Particles" authored by myself, Mark Albrecht and Mike  
23 Reed. Ah, yes. This is a study that I designed and  
24 conducted, in which I used the previously mentioned particle  
25 counter to look at particle counts in a laminar flow

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2 operating room, specifically with a reference to the  
3 boundary of the laminar flow zone.

4 Q. When was this done?

5 A. I do not remember, but it's likely it was done  
6 after February 2010, because this was done in -- not  
7 Wansbeck Hospital. In North Tyneside Hospital? Another  
8 trust. Another trust, another hospital in the same trust.

9 Q. Was it ever published?

10 (Reporter clarification.)

11 A. I said another hospital in the same trust. I don't  
12 remember if this was ever published. There was a similar  
13 experiment which I did, looking at particle counts in  
14 relation to different surgical garments that healthcare  
15 professionals could wear in an operating room, which was  
16 published, but I don't think this one was published.

17 Q. Do you know if it was presented at any --

18 A. I don't -- I don't think so.

19 Q. Can I have that exhibit sticker please? There we  
20 go, lucky 13.

21 (Exhibit 13 marked for identification)

22 Q. Dr. McGovern, I'm going to show you what has been  
23 marked as exhibit 13. It is a document bearing Bates number  
24 Augustine 0019943 through 44.

25 A. Yes.

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2 Q. -- it looks like it's an exchange of e-mails  
3 between Dr. Augustine and Tom Durick, and you were copied on  
4 them.

5 A. Yes.

6 Q. Do you recall getting these?

7 A. I do.

8 Q. And this is dated August 2, 2016.

9 A. Yes.

10 Q. So it is a little later than the June ones we were  
11 looking at.

12 A. Yes.

13 Q. In the last e-mail, or the latest e-mail, he says:

14 "Paul, if you could get back to Tom and  
15 perhaps get your draft to him for comments, that would  
16 be fantastic."

17 A. Yes.

18 Q. Do you know what draft he was referring to?

19 A. I believe he's referring to the paper which was  
20 sent to me with my name on it, which I had no involvement in  
21 writing.

22 Q. You mean the one that Augustine ghost wrote?

23 A. The one that was sent to me. I don't know if it  
24 was Augustine or one of his employees or colleagues that  
25 wrote it, but the one that was sent to me with my name on

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2 it, that I had no involvement in writing.

3 Q. You hadn't subsequently written your own draft; is  
4 that right?

5 A. That is correct. I had not edited that document in  
6 any way, or started work on looking at it in any detail at  
7 all.

8 Q. Since August 2, have you had any further  
9 communications with Augustine or Durick?

10 A. Not to my memory. It's possible that Tom Durick  
11 and I may have exchanged e-mails again, as I mentioned  
12 before. But if we have, it's not progressing things any  
13 more than this. It would have been a check-in to say, "How  
14 are you getting on? What's going on with this?" But this  
15 has not progressed in any way from this point.

16 Q. Would either Durick or Augustine have any reason to  
17 think that you're not doing anything further on it?

18 MR. SACCHET: Objection to form.

19 A. Would they have any reason to think I was not doing  
20 anything on it?

21 BY MR. C. GORDON:

22 Q. Right.

23 A. I haven't told them that I'm not doing anything on  
24 it. My silence is really speaking volumes, I suspect.  
25 I mean, I don't know how they've interpreted my lack of

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2 communication on it. They may think I'm furiously beavering  
3 away, toiling night and day on it, but I don't see why  
4 they'd think that. This has fallen by the wayside for me,  
5 and it's not really something that I'm interested in.

6 MR. C. GORDON: Okay, thank you. I have no  
7 further questions.

8 THE WITNESS: Thank you.

9 THE VIDEOGRAPHER: This is the end of DVD 4 in  
10 volume 1 of the position of Dr. Paul McGovern. Going off  
11 the record at 5:54. The recording has stopped.

12 (5:54 p.m.)

13 (Whereupon, the deposition concluded.)  
14  
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25

## 1 CERTIFICATE OF COURT REPORTER

2  
3 I, Louise Pepper, an Accredited Real-time Reporter, hereby  
4 certify that the testimony of the witness Dr. Paul McGovern  
5 in the foregoing transcript, numbered pages 1 through 229,  
6 taken on this 4th day of January, 2017 was recorded by me in  
7 machine shorthand and was thereafter transcribed by me; and  
8 that the foregoing transcript is a true and accurate  
9 verbatim record of the said testimony.

10  
11  
12 I further certify that I am not a relative, employee,  
13 counsel or financially involved with any of the parties to  
14 the within cause, nor am I an employee or relative of any  
15 counsel for the parties, nor am I in any way interested in  
16 the outcome of the within cause.

17  
18  
19 Signed: .....

20 Name: Louise Pepper

21 Date: January 10, 2017  
22  
23  
24  
25

## 1 CERTIFICATE OF DEPONENT

2  
3 I, Dr. Paul McGovern, hereby certify that I have read the  
4 foregoing pages, numbered 1 through 229, of my deposition of  
5 testimony taken in these proceedings on Wednesday, January  
6 4, 2017 and, with the exception of the changes listed on the  
7 next page and/or corrections, if any, find them to be a true  
8 and accurate transcription thereof.  
9

10 Signed: .....

11 Name: Dr. Paul McGovern

12 Date: .....  
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1 NAME OF CASE:

2 DATE OF DEPOSITION:

3 NAME OF WITNESS:

4 Reason Codes:

5 1. To clarify the record.

6 2. To conform to the facts.

7 3. To correct transcription errors.

8 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

9 From \_\_\_\_\_ to \_\_\_\_\_

10 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

11 From \_\_\_\_\_ to \_\_\_\_\_

12 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

13 From \_\_\_\_\_ to \_\_\_\_\_

14 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

15 From \_\_\_\_\_ to \_\_\_\_\_

16 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

17 From \_\_\_\_\_ to \_\_\_\_\_

18 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

19 From \_\_\_\_\_ to \_\_\_\_\_

20 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

21 From \_\_\_\_\_ to \_\_\_\_\_

22 Page \_\_\_\_\_ Line \_\_\_\_\_ Reason \_\_\_\_\_

23 From \_\_\_\_\_ to \_\_\_\_\_

24

25

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

IN THE MATTER OF )  
)  
IN RE BAIR HUGGER FORCED AIR )  
WARMING )  
PRODUCTS LIABILITY LITIGATION )  
)  
Plaintiff, )  
) PRETRIAL ORDER NO: 7  
v. ) Protective Order  
) MDL No. 15-2666  
3M COMPANY AND ARIZANT ) (JNE/FLN)  
HEALTHCARE INC. )  
Defendant. )

DEPOSITION OF PAUL MCGOVERN

VOLUME II

Thursday, January 5, 2017

AT: FAEGRE BAKER DANIELS LLP

Taken at:

7 Pilgrim Street

London EC4V 6LB

United Kingdom

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Louise Pepper: Accredited Real-time Reporter

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JOB NO. 117121

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1 DR. PAUL MCGOVERN

2 P R O C E E D I N G S

3 THE VIDEOGRAPHER: This is Day 2 of the deposition  
4 of Dr. Paul McGovern. The deposition started yesterday  
5 4 January, today is 5 January 2017, and it is 9:24 a.m.  
6 This is the beginning of DVD 1 in volume 2 of Dr. McGovern's  
7 deposition. Everybody who was in the room yesterday is here  
8 today.

9 Can I remind the witness he was sworn in  
10 yesterday and is still under oath. Can you --

11 THE WITNESS: Yes.

12 THE VIDEOGRAPHER: You're on the record, counsel.  
13 It is 25 past 9.

14 EXAMINATION BY MR. SACCHET:

15 BY MR. SACCHET:

16 Q. Good morning, Dr. McGovern.

17 A. Good morning.

18 Q. As I mentioned yesterday, my name is Mr. Sacchet,  
19 and I represent the plaintiffs 3M. Yesterday my learned  
20 friend on the other side reviewed some of the ground rules  
21 for the deposition. I'm going to go through few more today,  
22 just to make sure we're on the same page with respect to the  
23 procedures for our conversation. As you know, I'll be  
24 asking you questions under oath and you'll be responding to  
25 them. If at any time you don't understand a question or if



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2 you don't hear the question, please let me know, okay?

3 A. Yes.

4 Q. As was mentioned yesterday, it's best for the  
5 record and the court reporter, if I ask a question, that you  
6 let me finish asking the question before you answer, and  
7 I'll do the same with respect to you in refraining from  
8 asking a question before you've finished your answer.

9 Please provide audible "Yes" or "No" answers with respect to  
10 the questions as opposed to a nodding or shaking of the  
11 head. Is that agreeable?

12 A. Yes.

13 Q. And if at any time you need a break, just let me  
14 know, and I'll find an appropriate spot to pause.

15 A. Sure.

16 Q. Before we jump into your background, with respect  
17 to your educational and professional history, just a few  
18 preliminary items. You've never met me before, have you?

19 A. Not before yesterday, no.

20 Q. And prior to yesterday, you'd never spoken to me  
21 before, be it via e-mail or phone?

22 A. That is correct.

23 Q. You've never spoken to any members of the  
24 plaintiff's counsel in this matter, have you?

25 A. That is correct.

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2 Q. Have you ever spoken to anyone on the side of the  
3 defense, prior to yesterday?

4 A. I'd received communications from various people on  
5 the side of the defense. I have only communicated with them  
6 through my lawyers.

7 Q. Okay. Do you recall who those individuals were  
8 that attended the --

9 A. Stephen Llewellyn, from Faeger Baker Daniels.  
10 I received a Linkedin message from a lawyer in the United  
11 States, but I don't remember their name.

12 Q. Do you recall the content of the message?

13 A. It was similar to the initial contact from Stephen  
14 Llewellyn, saying that 3M would like to depose me, and  
15 asking me to get back in touch to arrange that.

16 Q. And did you get back in touch to arrange that?

17 A. I did not reply to the Linkedin message at all, and  
18 I replied to Stephen Llewellyn through my lawyers when  
19 I arranged legal representation.

20 Q. Okay. So other than contact via your attorney,  
21 you've had no personal contact with anyone on the other  
22 side?

23 A. That is correct.

24 Q. I know you spoke a little bit yesterday about your  
25 background as well, and I'm going to review some of that

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2 material with you. So to the extent that any of my  
3 questions repeat questions that were asked, I appreciate  
4 your patience, but I'd like to make sure that we're on the  
5 same page with respect to both your educational and  
6 professional background.

7 A. No problem.

8 Q. You enrolled to University College of London  
9 otherwise known as UCL; correct?

10 A. Correct. At the time I enrolled, it was known as  
11 Royal Free and University College Medical School. It's now  
12 known as University --

13 (Reporter clarification.)

14 A. That's now changed its name to University College  
15 London Medical School, and it's in the University of London.

16 Q. And you first enrolled in 2000?

17 A. Correct.

18 Q. What was your academic focus at the time?

19 A. In the UK, medical students enter medical school  
20 straight from school. So I finished school at 18 and  
21 immediately went to medical school. The program is rather  
22 different in the UK compared with what I understand it is in  
23 the States. There is no pre-degree program.

24 Q. Okay.

25 A. You go straight to medical school, and so the focus

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2 then was medicine. I did do an undergraduate degree, in  
3 addition to my medical degree, in the University of  
4 Manchester, in Healthcare Ethics and Law in 2003/4, and then  
5 returned to my studies in medicine, completing in 2006.

6 Q. So when you went to University of Manchester, is  
7 that when you obtained your BSC?

8 A. Correct.

9 Q. Okay. And the BSC was specializing in healthcare  
10 and ethics law?

11 A. Healthcare ethics and law.

12 Q. Okay. When you obtained your BSC, was part of the  
13 curriculum taking courses, I assume in science, but more  
14 specifically surgery?

15 A. The way the BSC works is it's called an  
16 intercollated BSC, and that's a BSC on offer to medical  
17 students. The first two years are in basic medical sciences  
18 and were undertaken at UCL.

19 Q. Okay.

20 A. The third year BSC may have the appearance of doing  
21 a Bachelor's Degree in one year, but you have some credit  
22 from the first two years of basic medical sciences. And so  
23 the BSC year itself was only in healthcare ethics and law.  
24 But my basic medical training gave me medical related  
25 background, as it would for any other doctor in the UK.

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2 Q. So what were some of the classes with respect to  
3 the basic scientific training that you undertook?

4 A. So medical training at the medical school I went to  
5 is integrated. It is a course which focuses on systems, but  
6 within that, the traditional disciplines of physiology,  
7 biochemistry, microbiology, immunology, basic medical  
8 statistics, ethics, relevant medical law, men's health,  
9 women's health, will have been taught -- were taught --  
10 organized by Body Systems. So foundations of health and  
11 disease, foundation of medical practice, looking at cell  
12 function, cell biology, pharmacology. So the actions of  
13 drugs on the body, and the actions of the body on drugs.  
14 Infection and defense. Cardiorespiratory systems and  
15 digestive systems. That will be in the first year.

16 And in the second year, from memory, I can't  
17 remember the exact --

18 Q. That was a long list. You can just give me a few.

19 A. That's fine, I can keep going.

20 Q. So with respect to the class you took in medical  
21 statistics, was that kind of a foundational class where you  
22 learned rudimentary statistics?

23 A. Very basic. It was a very basic class.

24 Q. So you're familiar with confidence intervals?

25 A. I'm familiar with terms, but I don't pretend to

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2 have any expertise in statistics.

3 Q. Are you familiar with P values?

4 A. Yes.

5 Q. And you understand that P values generally,  
6 statistical significance is determined at 0.05 --

7 (Reporter clarification.)

8 Q. With respect to P values, you're aware of the fact  
9 that statistical significance is generally determined at a P  
10 value of 0.5?

11 A. By convention, yes. Statistical significance is  
12 determined at a P value of 0.5. That's essentially an  
13 arbitrary figure, but it's been accepted at what is  
14 generally considered to be statistical significance.

15 Q. Would a P value of 0.6, or something to the effect  
16 of .09, still in your mind be something enough to be nearly  
17 significant, even though it's not at 0.05, the traditional  
18 cut-off?

19 A. The question of nearly significant is -- although  
20 the cut-off is arbitrary, something is not quite as  
21 significant -- as statistically significant unless it  
22 reaches a P value of 0.05. So I would not use terms in  
23 a scientific or in an professional sense such as "nearly  
24 significant" or "nearly statistically significant". I may  
25 talk about -- I may use those terms informally in

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2 discussions with colleagues, but in scientific discourse,  
3 something statistically significant or it is not, as far as  
4 I'm concerned.

5 Q. Okay. When you went back to UCL, was your training  
6 similar to kind of the scientific curriculum that you did  
7 prior to going back to UCL?

8 A. It was a continuation of the same program. The  
9 first two years, at the time that I trained, were more  
10 pre-clinical in their focus, but there was still clinical  
11 exposure -- early clinical exposure at that medical school.  
12 When I went back, yeah, in the first -- one year before  
13 I went to Manchester, I started clinical training. I went  
14 to Manchester and then came back and completed two further  
15 years of clinical -- clinically focused training. So that  
16 was an apprentice-style training where I learned on wards in  
17 family doctors' surgeries in a practical environment.

18 Q. Okay. And when you were at UCL in 2006, that's  
19 when you obtained your MBBS?

20 A. Correct. MBBS: Bachelor of Medicine and Bachelor  
21 of Surgery.

22 Q. After you obtained your MBBS, were you required to  
23 take any examinations similar to what we'd have in the  
24 States called board exams, to take a further step, or had  
25 you already taken those types of exams to enroll at UCL and

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2 the University of Manchester?

3 A. The -- do you mean to become -- to qualify as  
4 a doctor?

5 Q. Yes.

6 A. So at the end of the program of medical training,  
7 one has to sit final medical school exams to be awarded the  
8 degree of MBBS.

9 Q. Okay.

10 A. Once awarded that degree, assuming that there are  
11 no fitness to practice issues or other issues which would  
12 question the fitness of the doctor to practice in the UK,  
13 one is awarded provisional registration with the General  
14 Medical Council, which is the professional body regulating  
15 doctors in the UK. And so I was allocated a place in  
16 a hospital to become a doctor before I qualified, but I  
17 passed my final exams, and that gave me access to that post,  
18 and received provisional registration with the GMC, which is  
19 standard practice in the UK.

20 Q. Got it. When you were given this provisional  
21 position that eventually turned into a position once you  
22 pass these exams, were you what is called a foundation  
23 doctor? A house doctor?

24 A. When I started in August 2006 at Basildon Hospital,  
25 I was a foundation year one doctor; that's correct.



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2 Q. And as a foundation year one doctor, what did your  
3 surgical training entail?

4 A. My foundation year one training was split between  
5 six months of surgery and six months of other medical  
6 specialties. So I did six months in breast and general  
7 surgery -- sorry, incorrect -- three months in breast and  
8 general surgery; three months in gastroenterology, that's  
9 medicine; three months in psychiatry, in adult psychiatry;  
10 and three months in trauma and orthopedics.

11 Q. Okay. And the three months in trauma and  
12 orthopedics, that was surgically related, not just studying  
13 abstractly?

14 A. Correct. Those three months -- or the six months  
15 in surgery, those in general surgery and breast surgery and  
16 trauma and orthopedics, were mainly ward-based, as a junior  
17 doctor, but also in the operating room assisting with  
18 surgical procedures. So I was a practicing doctor under  
19 supervision.

20 Q. In total, whether they were breast surgeries,  
21 orthopedic surgeries, whatever they may have been, how many  
22 surgeries do you believe you witnessed?

23 A. Witnessed in those six months?

24 Q. Yeah.

25 A. Dozens.

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2 Q. Hundreds?

3 A. Probably not hundreds. Probably -- it's very  
4 difficult to say accurately, because I did not start keeping  
5 a logbook until later on in my career. I would say in the  
6 order of 50 to 100, but that's quite a guess.

7 Q. When you were just a house doctor, prior to  
8 becoming a registrar, did you assist in any surgeries?

9 A. Yes.

10 Q. You did. And how many, approximately, do you think  
11 you assisted in?

12 A. I would assist, in the six months I was in surgical  
13 practice, and also sometimes I was -- when I was working in  
14 psychiatry, I would assist in theaters, in the operating  
15 room, two or three times a week, maybe for two surgeries.

16 Q. Okay.

17 A. It's very difficult to know exactly how many  
18 surgeries I assisted in. I would try to assist as much as  
19 possible. I would tend not to observe on the sidelines. I  
20 would -- the term is "being scrubbed", but actually being in  
21 the operation and assisting as first or second assistant.  
22 And I would -- as I was interested in surgical practice, I  
23 made every effort to be as involved in, and to scrub for, as  
24 many procedures as I could.

25 Q. During the three-month stint where you were first

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2 involved in orthopedic surgery as a foundation doctor, were  
3 you training with Mr. Mike Reed at that time?

4 A. I was not.

5 Q. So you only trained with Mr. Mike Reed when you  
6 were a registrar?

7 A. No, I only trained with Mr. Mike Reed when I was  
8 what's called a core surgical trainee, when I moved to the  
9 North of England in two thousand and -- well, I moved to the  
10 north of England in 2008 and I started working with Mike  
11 Reed in 2009.

12 Q. Okay. Would you consider Mr. Mike Reed an expert  
13 in orthopedics?

14 A. I would.

15 Q. He has published tens, if not hundreds, of  
16 peer-reviewed articles on orthopedics?

17 A. He's published many articles. I don't know how  
18 many.

19 Q. And you obtained your certificate of completion,  
20 I believe it's called, in 2010; is that correct?

21 A. I obtained a certificate of basic -- I completed  
22 basic surgical training in 2010. That's very different from  
23 a certificate for completion of training. I have not  
24 received what's called a CCT in surgery. That would mean  
25 that I was at an attending level, and I have not received

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2 a CCT. But I did complete successfully, and received the  
3 relevant documentation that I had completed basic surgical  
4 training.

5 Q. And you eventually became a registrar specializing  
6 orthopedics; correct?

7 A. That's correct.

8 Q. Okay. And that occurred in 2010?

9 A. That occurred -- I think it may be April 2011.

10 Q. Okay.

11 A. Yeah, I started in that role in April 2011.

12 Q. And that was after the time in which you first  
13 conducted the experiment regarding particles and bacteria  
14 that was discussed yesterday; correct?

15 A. That is correct.

16 Q. So when you performed that study, you were  
17 a foundation doctor?

18 A. No, when I -- so in the UK, the first two years of  
19 practice are foundation year, foundation year one and two.  
20 Some doctors, confusingly, do a foundation year three, but  
21 the general track is to go from a foundation year two to  
22 core training year one. And I did core training year one  
23 and two, so I was a core surgical trainee, sometimes known  
24 as a senior house officer. There are two different  
25 terminology systems that -- senior house officer grade is an

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2 old grade which has been superseded, but is still used in  
3 common parlance in hospitals. But I was a core surgical  
4 trainee at the time that I was working with Mr. Mike Reed  
5 and doing these studies. So I had specialized in surgery at  
6 that point.

7 Q. So whether you were a core trainee or a registrar  
8 specializing in orthopedics, how many surgeries do you think  
9 you performed during that time?

10 A. During the time as a registrar, or?

11 Q. Maybe all told, both as a core trainee and  
12 a registrar?

13 A. In total, as a doctor, I've performed over  
14 a thousand surgeries. I would have to check my logbook to  
15 confirm that number, but I have performed, supervised or  
16 unsupervised, probably over a thousand surgeries.

17 Q. And the majority of those relate to orthopedics?

18 A. The majority will relate to orthopedics. Or there  
19 is some in plastic surgery which are fairly relatable to  
20 orthopedics, because there is quite a lot of hand surgery in  
21 that. Some are in general surgery, but the majority are in  
22 trauma and orthopedics.

23 Q. And of those, the majority of those are hip and  
24 knee arthroplasties?

25 A. No, there is a sizable proportion that are hip and

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2 knee arthroplasties, but probably the bulk of the work was  
3 trauma. So that was emergency surgery which does include  
4 a large amount of hip arthroplasty or hemiarthroplasty,  
5 which is a similar operation but has a slightly different  
6 focus when doing it in a trauma situation. But I have  
7 worked specifically in hip firms, or hip jobs, and knee jobs  
8 throughout -- through my training. So I have had periods of  
9 six months focused on the knee and focused on the hip, in my  
10 training.

11 Q. In addition to performing surgeries on both hips  
12 and knees and other orthopedic matters, you've done a number  
13 of academic presentations to various organizations or  
14 entities; correct?

15 A. That's correct.

16 Q. One of those includes the British Hip Society?

17 A. That's correct.

18 Q. One of those includes the European Federation of  
19 National Associations of Orthopaedics and Enterology?

20 A. E4 -- yes.

21 Q. One of those includes the American Association of  
22 Orthopedics and Surgery?

23 A. Orthopedic surgeons, yes.

24 Q. Any others?

25 A. I've presented at several regional meetings. I've

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2 presented at the Association for the Study of Medical  
3 Education. I've presented at the -- another medical  
4 education conference in Milan called AMEE. I can't remember  
5 what that stands for. I think I've presented at another  
6 meeting, but I can't quite remember where that was.  
7 I think, yes, the British Trauma Society I presented at, and  
8 several presentations in the course of my work as an  
9 education consultant and an academic -- well, a Medical  
10 Education Fellow at UCL. But in orthopedics, those are the  
11 ones that I can remember off the top of my head.

12 Q. You've published at least six or seven  
13 peer-reviewed articles in your career thus far; correct?

14 A. Yes, at least.

15 Q. One of those includes Forced-Air Warming and Ultra  
16 Clean Ventilation Do Not Mix, in which you were the first  
17 author, correct?

18 A. Yes, correct.

19 Q. Another is Development of Electronic Software for  
20 the Management of Trauma Patients on the Orthopaedic Unit?

21 A. Correct.

22 Q. And another is Patient Warming Excess Heat: the  
23 Effects of Orthopedic Operating Room Ventilation  
24 Performance?

25 A. Yes.

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2 Q. Another is Forced-Air warming Design Evaluation of  
3 Intake Filtration, Internal Microbial Build-up and Airborne  
4 Contamination Emissions?

5 A. Yes.

6 Q. Another is Surgical Excision of Ununited Hook of --

7 A. Hamate.

8 Q. -- Hamate fractures, the Other Carpal Tunnel  
9 Approach?

10 A. Yes.

11 Q. Another is the Influence of Surgical Hoods and  
12 Togas on Airborne Particle Concentration at the Surgical  
13 Site, an Experimental Study?

14 A. Yes.

15 Q. Another is Bilateral DCIS Following Gynaecomastia  
16 Surgery?

17 A. Gynaecomastia surgery, yes.

18 Q. You know, when I was searching Google Scholar I saw  
19 another paper that I don't think was authored by you, but  
20 I want to be sure, even though a "P McGovern" appeared on  
21 the paper. And it is entitled, or it deals with  
22 thromboembolisms?

23 A. Is it hematology?

24 Q. Yes?

25 A. That's not me.



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2 Q. Okay. I didn't think it was.

3 A. Can you just read the name of the paper?

4 Q. Yeah. Anticardio Lipin Antibodies --

5 A. No, that's not me.

6 Q. The purported "P McGovern" was a student at the  
7 University of Minnesota, which I assumed you didn't attend,  
8 but I know you had traveled there. So I was curious if at  
9 one point in time you'd had maybe a short stint there.  
10 Thanks for clarifying that. Any other publications  
11 involving orthopedics other than the ones I've mentioned?

12 A. I have co-authored a textbook which is regarding  
13 surgery, and I was particularly focused on orthopedics.  
14 That was a revision aid for medical students published by  
15 Oxford University Press. One of the poster presentations at  
16 the British Hip Society in -- regarding this area won  
17 a prize. I think that was looking at filtration adequacy of  
18 forced-air warming units. I don't have the name of the  
19 poster off the top of my head, but --

20 Q. Do you know the name of the prize?

21 A. No, I can't remember the name of the prize. It was  
22 commended.

23 Q. With respect to the textbook that you mentioned,  
24 who invited you to edit the textbook that was eventually  
25 published in Oxford University Press?

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2 A. The series editor of the -- yeah, the series editor  
3 of the textbook series representing Oxford University Press.

4 Q. Do you know why that individual reached out to you  
5 specifically?

6 A. Yes. I have quite a lot of experience in examining  
7 and writing and designing test assessment exercises for  
8 medical students and for doctors, and I had worked with this  
9 individual in constructing and designing assessments for the  
10 General Medical Council to assess doctors who -- whose  
11 fitness to practice has been called into question. And  
12 because I had done quite a lot of work in designing those  
13 assessments, the series editor asked me to help with this  
14 project as it had somewhat stagnated; and I was asked to  
15 come in and help finalize reviewing and get the project  
16 moving again so that it could be published.

17 Q. Did -- I think you mentioned this, but I want to be  
18 sure. Did any of the content in that textbook specifically  
19 relate to orthopedics?

20 A. It did.

21 Q. In what way?

22 A. The textbook is a question -- a 'single best  
23 answer' question book for medical students to practice  
24 answering exam questions for medical school finals. Some of  
25 the questions are written above the level of medical school

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2 finals, for bright students to be able to test themselves.  
3 But it covers all areas of surgery that are likely to be  
4 encountered by medical students in final exams, and  
5 orthopedics is a component of that. And so, some of the  
6 questions in that book, to my recollection, were on  
7 orthopedics and trauma.

8 Q. Okay. And some of those questions dealt with  
9 surgical procedure, in terms of how to perform surgeries or  
10 more academic content base of --

11 A. The content of those questions, I would have to  
12 revisit it to be absolutely sure, but generally, if I'm  
13 teaching medical students, I want them to understand the  
14 principles behind surgical practice rather than operative  
15 procedures. And so any focus for questions, testing medical  
16 students would be aligned with that -- with that aim.

17 Q. Was the textbook published?

18 A. It was.

19 Q. Back a little bit to the articles we were  
20 discussing further, do you consider yourself to have  
21 a well-rounded understanding of the peer-review process?

22 A. Yes.

23 Q. Do peer-reviewed articles hold more weight than  
24 non-peer-reviewed articles?

25 A. I think the general consensus among clinicians

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2 would be yes, peer-reviewed articles hold more weight than  
3 non-peer-reviewed articles.

4 Q. And is that because independent editors of those  
5 journals evaluate the articles and determine whether they  
6 are worthy of publication in a journal?

7 A. Yes. Well, the peer-review process will tend not  
8 to start with the editor. Some journals will -- the editor  
9 will screen things; some journals will have an automatic  
10 peer-reviewed process. The article will go to peer review  
11 and be scrutinized, generally anonymously, by appropriately  
12 qualified specialists in the field, and they will comment as  
13 to whether they think the paper is not appropriate for  
14 publication, or may be appropriate for publication pending  
15 changes, which is the most common option, or appropriate for  
16 publication wholesale. That feedback will go back to the  
17 editor, who will generally make a final decision as to  
18 whether the article should be recommended for publication  
19 pending alteration, or rejected but the authors being  
20 invited to resubmit -- depending on the process of the  
21 individual journal.

22 Q. When an article actually is published in a journal  
23 that has been peer-reviewed, that signifies that experts  
24 have reviewed the article and determined it should be  
25 published; correct?

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2 A. Correct.

3 Q. And you've worked with Mr. Reed on some of the  
4 articles that you participated in authoring that had been  
5 published in peer-reviewed journals; correct?

6 A. That's correct.

7 Q. You have the utmost confidence in -- you have the  
8 utmost confidence in Mr. Reed's ability to publish papers  
9 regarding orthopedic matters?

10 A. Yes, I have a great deal of respect for Mr. Reed's  
11 clinical acumen and experience.

12 Q. You have no reason to doubt Mr. Reed's expertise in  
13 the field of orthopedics?

14 A. None whatsoever.

15 Q. You have no reason to doubt anything that Mr. Reed  
16 might publish in a peer-reviewed journal?

17 A. No, none whatsoever.

18 Q. Did you know that 3M recently sponsored Mr. Reed to  
19 conduct a study in the UK with regarding orthopedics?

20 MR. C. GORDON: Object to the form of the  
21 question. Assumes facts not in evidence.

22 A. Could you repeat the question, please?

23 BY MR. SACCHET:

24 Q. Did you know that 3M recently sponsored Mr. Reed to  
25 conduct a study regarding orthopedics in the United Kingdom?

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2 A. I did not.

3 Q. But you would consider Mr. Reed an expert in  
4 orthopedics?

5 A. I would consider Mr. Reed an expert in orthopedics.

6 Q. You've also worked with Mr. Mark Albrecht on some  
7 of the articles we mentioned a few minutes ago; correct?

8 A. That's correct.

9 Q. Mr. Albrecht helped design, conduct or write the  
10 papers that were eventually published in those journals?

11 A. The ones which had his name attached, yes.

12 Q. You have no reason to doubt Mr. Albrecht's ability  
13 to perform statistical analysis, do you?

14 A. None whatsoever.

15 Q. You have no doubt about Mr. Albrecht's ability to  
16 design a methodologically sound study, do you?

17 A. None whatsoever.

18 Q. You have no reason to doubt Mr. Albrecht's honesty  
19 in writing and navigating through the peer review process to  
20 publish a paper in a journal, do you?

21 A. No.

22 Q. You have the utmost confidence in Mr. Albrecht?

23 A. Yes.

24 Q. Mr. Reed similarly has confidence in Mr. Albrecht,  
25 and he has told you that before; correct?

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2 A. My impression is that Mr. Reed has confidence in  
3 Mr. Albrecht and holds him in high regard, but you'd have to  
4 ask Mr. Reed what his opinion of him is.

5 Q. Do you recall Mr. Reed informing a group of people,  
6 including you, that he was extremely impressed with  
7 Mr. Albrecht?

8 A. I -- that is consistent with -- I don't remember  
9 the specific event, but Mr. Reed has expressed that he has  
10 been impressed by Mr. Albrecht in the past, yes.

11 Q. You've served as a reference for Mr. Albrecht  
12 before in a professional capacity; correct?

13 A. That's correct.

14 Q. And that reference was with respect to  
15 Mr. Albrecht's application to the National Marrow Program?

16 (Reporter clarification.)

17 A. That's correct.

18 Q. You were aware, as well, that at one point in time  
19 3M offered Mr. Albrecht a job; correct?

20 A. I might have been told that. I don't remember  
21 that, speaking about it now, but it rings a bell. I can't  
22 remember if Mark Albrecht worked for, or was offered a job  
23 by, 3M.

24 Q. Would a document help refresh your memory?

25 A. That would help refresh my memory, yeah.

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2 (Exhibit 1 marked for identification)

3 A. Thank you very much.

4 Q. Do you see at the top of the e-mail there is --

5 A. Yes.

6 Q. -- a message to you from Mr. Albrecht, dated  
7 February 21, 2012, at 5:56 pm?

8 A. Yes.

9 Q. The subject line is "Bit of a wild ride with the  
10 job search"; correct?

11 A. Yes.

12 Q. And in the e-mail below that, which actually  
13 precedes the one that I just mentioned by just a few  
14 minutes, Mr. Albrecht wrote to you; correct?

15 A. He did, yes. That's right.

16 Q. And he says:

17 "So I thought I'd give you an update."

18 A. Yes.

19 Q. "Today I accepted a position as a Program Manager  
20 with National Marrow Donor Program in the bio-informatics  
21 group. Before that, I had an offer from 3M that I accepted,  
22 an offer that was rescinded based on my non-compete a week  
23 after I signed."

24 Do you see that?

25 A. I do see that, and I remember that now.



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2 Q. And that refreshes your recollection?

3 A. That does refresh my recollection.

4 Q. Would you consider Mr. Albrecht to be an expert in  
5 statistics?

6 A. Yes.

7 Q. Jumping back to your background just for a few more  
8 minutes, while you were at UCL, you were deemed an honorary  
9 lecturer; correct?

10 A. For a period of time, yes. I was initially  
11 appointed an honorary lecturer during my FY2 year, so that  
12 was 2007, I believe. And I have held an honorary or  
13 substantive post at UCL Medical School in some form, ever  
14 since.

15 Q. Is that common thing, for people that trained at  
16 UCL to be given that type of honorary position?

17 A. It's not. It's not common, and it is -- it's  
18 something I consider to be a significant privilege.

19 Q. I assume that to be nominated, and to hold such  
20 a position, the university recognizes some type of expertise  
21 that you hold?

22 A. Yes.

23 Q. And what do you think that expertise entails?

24 A. My original appointment was for anatomy  
25 demonstrating. So, I led a program organizing anatomy

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2 demonstrators in the region to come and provide surgical  
3 trainees to the medical school to demonstrate on anatomy and  
4 assist surgical trainings in their own training, because  
5 demonstrating is an excellent way to boost your own  
6 anatomical skills. I also developed, and ran for several  
7 years, a revision website based at the medical school for  
8 final-year medical students which involved mentoring  
9 students online, and editing and providing assessment  
10 exercises, exam style questions, for students so they could  
11 practice before their exams, answering questions based on  
12 those assessment exercises, and providing advice documents  
13 for students.

14 I also set up an education program at Basildon  
15 Hospital in Essex, which was the first of its kind with  
16 one -- with two colleagues, which was then rolled out to  
17 hospitals throughout the region, and is a model of best  
18 practice in medical education for what's known as  
19 near-peer learning in the region. And so my initial  
20 appointment, as a lecturer, was for surgical anatomy  
21 demonstrating, and my continued appointments were for  
22 medical education, both in general assessment and in  
23 orthopedic and surgical practice.

24 Q. So, all of that did involve orthopedic surgical  
25 practice?

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2 A. Yes. Well, it involved practice relevant to  
3 orthopedic surgery.

4 Q. Okay.

5 A. In some form, yes.

6 Q. Is any of the material you've just discussed the  
7 same as when you were a clinical teaching fellow, or was  
8 that a separate responsibility that entailed separate  
9 duties?

10 A. There is a crossover. So I have been an honorary  
11 teaching fellow for some years. I don't remember exactly  
12 when my lecturer position was changed to teaching fellow  
13 after my surgical role finished. In terms of academic rank,  
14 they are effectively the same. But I've been an employed  
15 substantive teaching fellow on two separate occasions, which  
16 had similar roles; but the first time I was employed in that  
17 role between August 2010 and April 2011, my role was leading  
18 undergraduate teaching in a hospital. And on the second  
19 occasion, between October 2013 and August 2016, I was  
20 working in post-graduate education and education  
21 consultancy.

22 There is a crossover between all of them,  
23 because, right up until 2016, I was still examining  
24 final-year medical students, teaching them orthopedics,  
25 teaching ethics and law to students. So, right

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2 throughout the whole of my teaching, there has been an  
3 orthopedic component to what I do in an educational  
4 capacity. But the amount varies, depending on the  
5 particular role that I'm engaged in at the time.

6 Q. Got it. Have you obtained an MRCS?

7 A. I have.

8 Q. What does that stand for?

9 A. MRCS is Membership of the Royal College of  
10 Surgeons.

11 Q. And being a Member of the Royal College of Surgeons  
12 designates what, to someone who has no understanding of the  
13 term?

14 A. It designates that someone has passed an exam set  
15 by all the Royal Colleges of Surgeons -- there are three  
16 Royal Colleges of Surgeons in the UK -- to meet the academic  
17 standards required to enter higher surgical training in the  
18 UK.

19 Q. And I assume some people that train initially in  
20 orthopedics don't pass the exam that would ultimately enable  
21 them to have the MRSC degree?

22 A. That's correct. So, when I did the exam, they were  
23 changing the exam style, and there were two styles. One was  
24 a new style and one was the old style. And the old style  
25 had a pass rate -- the new style had a pass rate of about 60

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2 percent and the old style had a pass rate of about 30  
3 percent. And I chose to take the old style, and passed that  
4 first time.

5 Q. So you were one of the approximately 30 percent of  
6 people who pass that exam?

7 A. Correct.

8 Q. Why did you choose to take the old style?

9 A. Because it was more of a challenge.

10 Q. Do you know anyone else that chose to take the old  
11 style, as opposed to taking the new style?

12 A. I don't.

13 Q. In your --

14 A. There were other people, because there were other  
15 people in my cohort, so presumably it has happened, but  
16 I don't personally know anyone.

17 Q. At one point in time, or potentially at the  
18 present, you were designated as an honorary orthopedic  
19 registrar; correct?

20 A. That's correct.

21 Q. And what does that mean, for the ladies and  
22 gentlemen of the jury?

23 A. Yes, so while I was a teaching fellow, I was  
24 still -- I still retained my status as a trainee orthopedic  
25 surgeon. This is in the second period of being an academic

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2 at UCL. There is a system called Out of Program Experience,  
3 or Out of Program Training, that allows doctors in training  
4 to retain their -- what's known as a National Training  
5 Number, their status as a training registrar, while doing  
6 academic work. And I received an honorary position at UCL  
7 hospitals which allowed me to continue to practice in  
8 orthopedics while I was doing academic work.

9 Q. I mean, can anyone get this designation that wants  
10 it, or is there a selection process by which UCL and the  
11 hospitals determine you can be an honorary orthopedic  
12 registrar?

13 A. The primary method of selection, the reason that  
14 I was able to get that role, was because I had completed the  
15 selection process for registrar training, which is extremely  
16 competitive. Once I have that status of becoming  
17 a registrar, then it is generally accepted that one can gain  
18 an honorary contract in the position that I was. The  
19 barrier to entry for that is becoming a registrar in the  
20 first place, which is extremely competitive.

21 Q. Given all your training that you had in orthopedic  
22 surgeries and other types of surgeries, you're well familiar  
23 with laminar flow?

24 A. I am -- I would consider myself with very familiar  
25 with laminar airflow.

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2 Q. For the ladies and gentlemen of the jury, can you  
3 briefly explain basic concepts about laminar airflow?

4 A. I can. So, with -- relevant to an operating room,  
5 a laminar airflow system is one in which the operating room  
6 has an area in the middle of it which is designated as  
7 specifically -- or as an especially clean area; and there is  
8 a device in the ceiling, in the roof of the operating room,  
9 which blows filtered air down over the patient and over the  
10 surgeons and the surgical staff. And the idea is that  
11 sterile air is blown down and clears away any contaminants,  
12 any airborne particles which could land in the wound of the  
13 patient and subsequently cause an infection.

14 Q. What types of filters are generally used in the  
15 ceiling vents by which the laminar airflow comes downward?

16 A. By my understanding, they are generally HEPA  
17 filters, which are filters specifically designed to filter  
18 out microbes or any particles which could be large enough to  
19 cause infection, or to have bacteria stick to them, which  
20 could cause infection. I would assume, in a correctly  
21 functioning laminar flow operating room, that the air that  
22 comes out of the laminar flow device is effectively sterile.

23 Q. HEPA filters block approximately 99.9 percent of  
24 particles size 0.3 microns or larger; is that your  
25 understanding?

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2 A. That is my understanding. There is a definition of  
3 the performance that a HEPA filter should meet to be  
4 classified as a HEPA filter. I don't remember the exact  
5 classification, but what you've just described sounds pretty  
6 much exactly what I would expect a HEPA filter to perform  
7 as.

8 Q. The basic purpose of laminar airflow is to decrease  
9 airborne microbial counts and move particles away from the  
10 surgical site; correct?

11 A. The fundamental reason for having laminar flow is  
12 to reduce infection rates. The mechanism by which it is  
13 thought to do that, is to reduce the concentration of  
14 airborne particles containing bacteria from the region of  
15 the patient and from the operative wound.

16 Q. No matter what surgical staff try to do, there is  
17 always going to be particles in the operating room; correct?

18 A. That is -- practically, yes.

19 Q. And some of those particles, whether they are, or  
20 whether they carry, have bacteria on them?

21 A. Yes.

22 Q. -- in the operating room. And bacteria pathogens,  
23 whatever you might call them, those are the things, the  
24 bugs, that cause the infection; correct?

25 A. Yes.



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2 Q. Large inoculums of germs are required to cause  
3 soft-tissue infections; correct?

4 A. It depends on the clinical make-up. If a patient  
5 has some degree of compromise to their immune system, if  
6 they have a pre-existing infection, if they have  
7 inflammation, if there is a problem in the soft tissue, then  
8 you -- then an infection may be precipitated by a relatively  
9 small inoculum or a relatively small dose of bacteria.  
10 However, in soft tissue, the chance of infection with  
11 a small amount of bacteria is very, very much lower than it  
12 is with implant or bone.

13 Q. In a normal, let's say -- call them healthy  
14 patient?

15 A. Yes.

16 Q. That doesn't have, you know, particular specific  
17 demographics that would make them particularly susceptible  
18 to an infection, you need a large inoculum of bacteria to  
19 cause a soft-tissue infection?

20 A. Generally.

21 Q. And as you mentioned, that's in stark contrast to a  
22 deep joint infection, which I'll probably refer as to "DJIs"  
23 in our conversation. But in a DJI, you only need a small  
24 load of bacteria to cause an infection?

25 A. The potential for causing infection with a small

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2 load of bacteria is very much higher when dealing with bone  
3 or artificial implants, yes.

4 Q. A single bacterium can cause a DJI?

5 A. As far as I'm aware, a single bacterium can cause  
6 a deep joint infection if it is in the wrong place.

7 Q. And the reason for that is a bacterium on an  
8 implant can and often does create biofilm?

9 A. It can create a biofilm. It depends on the  
10 bacterium and whether it creates a biofilm, so I wouldn't --  
11 it's quite a general description, and some bacteria are very  
12 prone to causing biofilms, which can cause more problems and  
13 make them -- make the infections they produce harder to  
14 treat.

15 MR. C. GORDON: Let me just interpose an  
16 objection. I think we've gone well beyond fact witness  
17 questions, and we have strayed into expert testimony, which  
18 I understood was to be off the --

19 MR. SACCHET: I'll note for the record yesterday  
20 that the same types of questions were asked of Mr. McGovern  
21 that even exceeded the style of question that I have asked  
22 today, such as the specific types of components of types of  
23 medications and what they are comprised of. So I don't  
24 believe I have exceeded any precedent that was asked of  
25 yesterday.

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2 BY MR. SACCHET:

3 Q. In any case, biofilms protect bacterium from  
4 antibodies and antibiotics; correct?

5 A. They can do.

6 Q. And biofilm allows for a long latency periods with  
7 respect to the proliferation of an infection; correct?

8 A. With long?

9 Q. Long latency periods.

10 A. What do you mean by that?

11 Q. An infection could be dormant, and not necessarily  
12 rise to a level in which it would be detectable for a number  
13 of months?

14 A. I think that the interaction between biofilms and  
15 how rapidly infection appears is probably beyond my --  
16 beyond the remit of what I would confidently be able to  
17 discuss.

18 Q. Fair enough. Have you ever heard of, or observed,  
19 an infection that arose many months after a arthroplasty was  
20 performed?

21 A. Yes.

22 Q. How long?

23 A. It can happen six months afterwards.

24 Q. Have you heard of year-long latency periods?

25 A. Yes.

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2 Q. What's the longest you've heard of?

3 A. I would say within the order of a year.

4 Q. And you mentioned this before, but some particular  
5 patients have particular susceptibility to deep joint  
6 infection; correct?

7 A. Yes.

8 Q. But even in those types of patients, the infection  
9 still requires a bacterium to enter the surgical site;  
10 correct?

11 A. Any infection will require a bacterium to be in  
12 a place that it shouldn't be initially, yes.

13 Q. Deep joint infections can have devastating  
14 consequences for a patient; correct?

15 A. Absolutely.

16 Q. The artificial joint might need to be explanted?

17 A. Absolutely, yes.

18 Q. If it's explanted, the patient might need to stay  
19 in a hospital for an extended period of time in order to  
20 recover from the infection?

21 A. Absolutely.

22 Q. And there may very well need to be a reimplantation  
23 if there were an explantation; correct?

24 A. Correct.

25 Q. The total cost of that process can exceed £100,000?

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2 A. We tend not to deal in costs in the UK too much,  
3 because treatment is free, but the costs, to my  
4 understanding of deep joint infection, are gigantic, and  
5 I would not be surprised at a figure in excess of £100,000.

6 Q. Have you ever heard of a deep joint infection  
7 causing an amputation -- or requiring an amputation, I  
8 should say?

9 A. Yes, yes.

10 Q. How about death?

11 A. Yes.

12 Q. Given these devastating consequences, whether they  
13 be a reimplantation, an amputation, possible death, the  
14 quality of airflow in an operating room in an orthopedic  
15 procedure is of critical concern, is it not?

16 A. It is of significant concern to me as a surgeon in  
17 an operating room, yes.

18 Q. And the maintenance of the sterile field requires  
19 isolation from potential sources of contamination in the  
20 operating theater; correct?

21 A. Yes.

22 Q. You've said that statement to the Academy of  
23 Orthopedic Surgeons; correct?

24 A. I don't remember, but -- I don't remember saying  
25 that, but I agree with that sentiment.

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2 Q. So, at the end of the day, the bottom line is you  
3 want to reduce the presence of pathogens near the surgical  
4 site; right?

5 A. Correct.

6 Q. And that is the purpose of laminar airflow?

7 A. Yes.

8 Q. Laminar airflow is nearly universal in the UK in  
9 orthopedic procedures?

10 A. To my understanding, particularly in joint  
11 procedures. Not all orthopedic procedures will require  
12 laminar airflow, but it is predominant, in my understanding,  
13 for a joint-replacement surgery.

14 Q. And numerous studies have proven the efficacy of  
15 laminar airflow in decreasing bacterial counts near the  
16 surgical site; correct?

17 A. "Proven" is a very strong word.

18 Q. Found to be statistically significant?

19 A. To my knowledge, yes.

20 Q. One of those studies, and perhaps the first study,  
21 was the 1980s study by Lidwell, in which a randomized  
22 control style was conducted --

23 (Reporter clarification.)

24 Q. Lidwell conducted a randomized controlled trial and  
25 found a decrease in deep joint infection rates as a result

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2 of laminar airflow; correct?

3 A. Yes, I'm familiar with that paper.

4 Q. Your own research has shown that the concentration  
5 of airborne particles increases significantly outside the  
6 laminar airflow boundary?

7 A. Yes.

8 Q. That paper, or presentation, was entitled The  
9 Concentration of Airborne Particles Increases Significantly  
10 Outside the Laminar Airflow Boundary; correct?

11 A. That is the paper. I'm not sure if that's been  
12 peer-reviewed and published in a journal. If you can find  
13 that it has, then I am willing to accept it; but I don't  
14 remember if it has been.

15 Q. You would, I assume, be happy if I could find that?

16 A. I would be very happy if you could find it.

17 Q. In any case, you presented a presentation entitled  
18 as such to the American Academy of Orthopedic Surgeons?

19 A. I probably did. I can't remember all of the things  
20 that I've -- there's so many projects, that I can't remember  
21 which has been presented; but if I have, then I have, yes.

22 Q. Over time, the procedures for reducing particles  
23 near the surgical site have improved. Let me give you an  
24 example. The use of togas or spacesuits, as they're  
25 sometimes called, sometimes happens now, whereas it wasn't

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2 even a thing a couple of decades ago?

3 A. Yes. The manufacturer specifications for togas and  
4 spacesuits are often not declared as having reducing  
5 particle concentrations as an aim. They are marketed, to my  
6 understanding, as personal protective equipment. And  
7 however, they are used by orthopedic surgeons, in my  
8 anecdotal experience, to reduce shedding of particles and --  
9 because there is a perception that they increase -- or that  
10 they reduce the likelihood of infection. I am not sure that  
11 togas and hoods are designed to reduce particle counts.  
12 I believe exhaust suits are. I've not worked in an  
13 organization that uses exhaust suits. I'm aware that they  
14 have been used, and they are used, in some place places.  
15 But the intention of the surgeon in many cases in using  
16 hoods, togas, et cetera, is to reduce the possibility for  
17 infection.

18 Q. I mean, you published a paper evaluating particle  
19 counts with respect to the use of togas versus surgical  
20 gowns versus masks; correct?

21 A. Correct.

22 Q. And that study, which was peer-reviewed, found that  
23 the toga is the most effective in reducing particles near  
24 the wound site; correct?

25 A. It reduced particles in front of the surgeon at



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2 a position which was corresponding to where the wound site  
3 would be, yes.

4 Q. And togas, or spacesuits, whatever one calls them,  
5 were not typically used 20 years ago?

6 A. I don't know when they became more common, more  
7 commonly used. I don't know what timescale they have become  
8 more prevalent.

9 Q. Okay. In the toga study, as I may sometimes call  
10 it, you had a statement to the effect that particles could  
11 serve as a proxy for bacteria; correct?

12 A. That was the assumption that was used in the paper  
13 as a proxy for bacteria, or bacteria containing particles.

14 Q. And in addition to your own study, other scientists  
15 have similarly concluded that particles can be used to  
16 determine a percentage of bacteria from those particles;  
17 correct?

18 A. Correct.

19 MR. C. GORDON: Object to the form of the  
20 question.

21 A. I believe that other researchers and many surgeons  
22 would agree that particles can be used to infer likely  
23 bacterial loads.

24 BY MR. SACCHET:

25 Q. Are you familiar with the paper by Doctor Stocks,

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2 which you cited in your toga article?

3 A. I have seen it, but I don't remember the contents  
4 of it.

5 Q. But you are aware of other authors who have made  
6 the same conclusion that particles can be used as  
7 a measurement, whether --

8 A. I'm aware that that has been used in the past, and  
9 that that parallel has been drawn.

10 Q. In addition to the use of spacesuits, there are  
11 other things that can be done in orthopedic operating rooms,  
12 or otherwise, to reduce particles and bacteria at surgical  
13 site; correct?

14 A. Yes.

15 Q. One of those things are limiting movement in the  
16 operating room among surgical staff; correct?

17 A. Yes.

18 Q. Are there other procedures that you're aware of  
19 that have -- do the same?

20 A. That do the same? What --

21 Q. With respect to reducing particles, beyond  
22 spacesuits, beyond limited movement; things like that?

23 A. Controlling the temperature in the operating room  
24 may have effect. Humidity may have an effect. Reducing  
25 opening and closing of doors. The position of operating

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2 lights, in my research, has a marked effect on particle  
3 concentration. The use of forced-air warming device --  
4 devices, in my experience, has an influence on particle  
5 counts near the operative site, particularly when combined  
6 with overhead operating lights. And the presence of -- the  
7 number of people in the operating room, as well as their  
8 movement, influences it. The amount of kit, the heat  
9 emitted by the kit, the amount -- the type of surgery,  
10 because some surgeries produce particles: if you're  
11 operating on bone, then dust is produced. Sometimes there  
12 can be mists from electrocautery machines, from other  
13 equipment. Fluids can spray. All these things can  
14 influence airflows and particle counts in the region of the  
15 operative field.

16 Q. Okay. Are you aware that deep joint infection  
17 rates in operating rooms increased in the late 1980s up  
18 until the 2000s?

19 A. I am aware --

20 MR. C. GORDON: Object to the form of the  
21 question. Assumes facts not in evidence.

22 A. I'm aware that studies have shown that, or have  
23 indicated that.

24 BY MR. SACCHET:

25 Q. Do you think, given your experience in orthopedic

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2 operating rooms and your knowledge of laminar airflow, that  
3 laminar airflow is the culprit of the rising infection rates  
4 from the 1980s to 2000?

5 MR. C. GORDON: Same objection.

6 A. Laminar airflow in itself?

7 BY MR. SACCHET:

8 Q. Yeah.

9 A. I do not.

10 Q. Do you think that forced-air warming, which  
11 I believe you mentioned just a couple of minutes ago, has  
12 impacted the rising infection rate during that time period?

13 MR. C. GORDON: Same objections.

14 A. I believe it's possible.

15 BY MR. SACCHET:

16 Q. You've encountered a lot of orthopedic surgeons who  
17 are concerned about the use of forced-air warming in  
18 orthopedic procedures; correct?

19 A. That is correct.

20 MR. C. GORDON: Please note a form objection.

21 BY MR. SACCHET:

22 Q. The Bair Hugger is a forced-air warming system;  
23 correct?

24 A. Yes.

25 Q. The filter of the Bair Hugger is on the bottom of

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2 the device?

3 A. I believe -- I think there are various designs of  
4 Bair Hugger blower devices, and I'd need to look at one to  
5 confirm exactly the location of the filter. I don't  
6 remember.

7 Q. Have you ever seen a Bair Hugger with a filter on  
8 the bottom?

9 A. I've seen many Bair Huggers, Bair Hugger blower  
10 units, and I remember the control panels and what they look  
11 like, but I don't remember where -- if the filter was on the  
12 bottom or the side.

13 Q. Whether it's on the bottom or the side, the device  
14 is often placed on the ground of the operating floor?

15 A. Can I clarify: are you asking where the exhaust --  
16 the blower unit is, or the intake is?

17 Q. The intake.

18 A. Yeah, the intake. I can't remember where the  
19 intake is. You asked if --

20 Q. Whether the blower itself is often placed on the  
21 floor?

22 A. It will be placed on a -- generally, on a stand  
23 which is very close to the floor. So less than a foot from  
24 the floor, generally.

25 Q. So whether the filter is on the side of the device

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2 or under the device, it's taking in air close to floor  
3 level; correct?

4 MR. C. GORDON: Object to the form of the  
5 question.

6 A. Generally, yes.

7 BY MR. SACCHET:

8 Q. And some of that air bypasses the filter; correct?

9 MR. C. GORDON: Object to the form of the  
10 question. Lack of foundation.

11 A. It depends on the specific filter unit, and I do  
12 not know if that's always the case. It's possible that air  
13 bypasses the filter, but I don't know what proportion of it  
14 does.

15 BY MR. SACCHET:

16 Q. You were a co-author on a paper that dealt with  
17 filtration efficiencies; correct?

18 A. I was, yes.

19 Q. And that paper, which we'll talk about later, found  
20 that the air filtration efficiency of the model 700  
21 Bair Hugger blower was approximately 63 percent; correct?

22 A. It did find that, yes.

23 Q. So if that's the filtration efficiency at the -- at  
24 let's say 0.2 microns, some particles are then passed  
25 through the filter; correct?

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2 A. Yeah, if the filtration efficiency is reduced, then  
3 some particles which the filter is intended to block are  
4 passing through that filter. That is how I understand that  
5 result.

6 Q. If some of those particles had bacteria on them  
7 that bypassed the filter, the bacteria could colonize inside  
8 the blower?

9 A. It's possible, yes.

10 Q. You're not aware of any other filters on the device  
11 beyond the intake filter, are you?

12 A. I am not. I don't have an intimate knowledge of  
13 the anatomy of a Bair Hugger blower unit, but I'm not aware  
14 of further filtration stages.

15 Q. You've never seen a filter at the hose end of the  
16 device?

17 A. No, that's correct.

18 Q. And you've never seen a filter inside the blanket?

19 A. That's correct.

20 Q. So it's possible that particulates or bacteria  
21 could pass through the blanket?

22 MR. C. GORDON: Object to the form of the  
23 question. Lack of foundation.

24 A. It is possible.

25 BY MR. SACCHET:

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2 Q. It's also possible, and in fact you have been in  
3 correspondence suggesting the same, that a large percent of  
4 the heat from the blower does not enter the body but is  
5 exhausted into the operating room; correct?

6 MR. C. GORDON: Object to the form of the  
7 question.

8 A. I do believe that, yes.

9 BY MR. SACCHET:

10 Q. More than 800 watts of what I'll say waste heat can  
11 enter the operating room from the Bair Hugger; correct?

12 MR. C. GORDON: Object to the form of the  
13 question. Lack of foundation; assumes facts not in  
14 evidence.

15 A. Yes, all the power of a blower unit, all of the  
16 heat is going into the operating room in some form. Even if  
17 it goes into the patient, there's a -- the patient is within  
18 the operating room as well. So, a proportion of heat will  
19 go into the operating room. A proportion of heat energy  
20 will go into the operating room, yes.

21 (Exhibit 2 marked for identification)

22 Q. I'm just going to try to refresh your recollection  
23 for a moment with the document that's being marked.

24 A. Thank you.

25 Q. If you could turn to page 3 of 3.



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2 A. Yes.

3 Q. The last e-mail is dated July 3, 2010, from you.

4 A. Yes.

5 Q. To Mark Albrecht?

6 A. Yes.

7 Q. In the penultimate paragraph, the e-mail states:

8 "The energy paper has a nice bit on the  
9 significantly higher efficiency of Augustine CWB than  
10 Arizant FAW."

11 What does "Augustine CWB" mean?

12 A. "Augustine" refers to the company, I believe  
13 Augustine Biomedical & Design, and "CWB" refers to, I think,  
14 conductive warming blanket.

15 Q. And is "Arizant FAW" likely the Bair Hugger?

16 A. "Arizant FAW" refers in this e-mail to the  
17 Bair Hugger device.

18 Q. You continue:

19 "I think the message can still be put  
20 strongly in the terms you mentioned i.e. FAW is  
21 inefficient and has a high power draw ask (compared  
22 with CWB), resulting in a potential loss into the OR  
23 environment in excess of 800W."

24 So would you agree that in some cases, the  
25 Bair Hugger does result in excess heat of 800 watts of

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2 energy?

3 A. Yes.

4 MR. C. GORDON: Object to the form of the  
5 question: lack of foundation, assumes facts not in evidence.

6 A. Yes.

7 BY MR. SACCHET:

8 Q. So whether by blowing air in the operating room, or  
9 allowing air through the blanket, it's possible that the  
10 Bair Hugger moves bacteria toward the surgical site;  
11 correct?

12 MR. C. GORDON: Object to the form of the  
13 question: lack of foundation, calls for speculation,  
14 incomplete hypothetical.

15 A. It is possible.

16 BY MR. SACCHET:

17 Q. You have demonstrated this effect with respect to  
18 bubbles in a number of videos that were posted on a blog for  
19 Northumbria; correct?

20 A. That's correct.

21 Q. One of those videos is this one, which I'll play  
22 for you, and counsel is welcome to walk around and watch it  
23 if he pleases. I have DVDs that can be marked the same.

24 (Exhibit 3 marked for identification)

25 Q. I'll play it first, and then we can talk about it.

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2 THE VIDEOGRAPHER: Do I need to record this?

3 MR. SACCHET: I'm not entirely sure how to do  
4 that. The sound will come through, so you will be able to  
5 hear it on the video, and it can be transcribed the same  
6 way.

7 (Audio from DVD):

8 "In this clip, the forced-air warming blanket  
9 is turned on and the light is positioned under laminar  
10 flow to illuminate the operative field. The majority  
11 of the contaminated air from beneath the drapes is  
12 cleared by laminar flow. However, potentially  
13 contaminated air can be seen in the disrupted laminar  
14 flow underneath the operating light. At this stage,  
15 very little contaminated air is seen in front of the  
16 surgeon in the region of the operative field. The  
17 presence of the anaesthetist further disrupts the  
18 laminar flow, allowing hot air from the forced-air  
19 warming blanket to rise. Within 10 seconds, there is  
20 an increase in the contaminated air underneath the  
21 operating light. Less than 20 seconds after the  
22 anaesthetist stands in front of the patient, there is  
23 a clear increase in contaminated air in front of the  
24 surgeon and in the region of the operative field."

25 MR. C. GORDON: Is that the whole --

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2 MR. SACCHET: That's the whole clip.

3 MR. C. GORDON: Did you just excerpt it yourself?

4 MR. SACCHET: No, this was taken directly from the  
5 production.

6 MR. C. GORDON: And that was the entire thing that  
7 was on the --

8 MR. SACCHET: This is entitled "The final  
9 demonstration of FAW." I think it is labeled on the  
10 envelope I gave you. And you're welcome to look at it later  
11 and determine that this is the accurate copy of such.

12 (Reporter clarification.)

13 MR. SACCHET: It's labeled on the --

14 A. "The accurate copy of such."

15 BY MR. SACCHET:

16 Q. Mr. McGovern, do you have any doubt that that is  
17 the full and complete copy of the video?

18 A. No, I recognize that as the video that I produced  
19 and placed on the Northumbria orthopedics blog.

20 Q. Did you narrate the video?

21 A. I did.

22 Q. Were you the anesthesiologist that appeared next to  
23 the screen?

24 A. I was taking the role of the anesthesiologist in  
25 that video, yes.

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2 Q. Was Mr. Reed the individual in the spacesuit?

3 A. Yes.

4 Q. To the extent anything was not evidenced by the  
5 narration that you provide, can you provide a quick summary  
6 of what was observed in the video?

7 A. What that video shows is a set-up in which  
8 a mannequin is placed on an operating table as though -- and  
9 prepared as though for surgery, in terms of surgical  
10 draping. A Bair Hugger blanket is placed over the mannequin  
11 in the position that it usually would be for surgery. And  
12 the drapes have been positioned to fashion an anesthesia  
13 screen which takes the form of surgical drapes being clipped  
14 to a higher level, which often happens in operating rooms;  
15 the idea being to slightly reduce the chance of any spatter  
16 from the operative site going on to the anesthetist or their  
17 equipment. The forced-air warming blanket is turned on in  
18 that clip, and the bubble generator discussed yesterday is  
19 active. The outlet of the bubble generator is near the head  
20 end of the simulated patient.

21 What the clip shows is that with the  
22 operating lights in a position which they may well be,  
23 to illuminate an operative field, the presence of the  
24 anesthetist, in combination with the position of the  
25 operating light, in combination with the energy emitted

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2 by the forced-air warming blanket, encouraged  
3 particles -- or encouraged, in this case, neutral  
4 density helium bubbles -- from the region of the  
5 patient or the model patient's head to find their way  
6 up, the front of the anesthetist, along the operating  
7 lights, and down into the region of the operative  
8 field.

9 Q. Were standard particles performed with respect to  
10 draping and placement of the patient and the Bair Hugger,  
11 and any other steps that were performed in the simulation?

12 A. The draping, the positioning of the Bair Hugger,  
13 the position of the operating lights, the position of the  
14 anesthesia screen, were all designed -- were all intended to  
15 replicate those which would be seen in a real operation.

16 Q. Mr. Reed supervising is in fact in the simulation;  
17 correct?

18 A. Could you repeat that, please?

19 Q. Mr. Reed supervised and was in fact present in the  
20 simulation?

21 A. That's correct. Mr. Reed was -- yeah, supervised  
22 the positioning of the patient and the draping, and the  
23 positioning of the Bair Hugger, and the position of the  
24 operating lights, and the positioning of the anesthetist,  
25 and of the operating table.

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2 Q. He had no concerns about the set-up?

3 A. None that I'm aware of.

4 Q. And you used bubbles in this video; correct?

5 A. That's correct.

6 Q. Bubbles are a type of particle; right?

7 A. The bubbles are, I would agree, a type of particle.

8 Q. And, as we discussed before, with respect to your  
9 toga study and other papers that have been published,  
10 particles can be a measurement of bacteria?

11 A. That is the assumption that we are using and that  
12 is the inference we are drawing when we are measuring  
13 particles and measuring bubbles in these experiments.

14 Q. So, if bubbles are a type of particle, and  
15 particles can measure bacteria, presumably the bubbles were  
16 attempting to measure bacteria; correct?

17 A. The bubbles were attempting to demonstrate the way  
18 air flows. Bubbles are not -- they are more a measure of  
19 where air flows, and they show where air has flown from and  
20 to. The inference, therefore, is that particles would be  
21 carried on the airflows, and the bubbles enable us to  
22 visualize where air starts and where air ends up. And so,  
23 the inference that we took from that experiment was that air  
24 was flowing from the area of the patient's head, a  
25 non-sterile zone, to what was considered a sterile zone, and

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2 that any light, airborne particles, we assumed would have  
3 been carried along that air current.

4 Q. And air generated from a non-sterile zone could  
5 have bacteria?

6 A. That's correct.

7 Q. And so it's possible that some of the particles  
8 that were being demonstrated through bubbles could have had  
9 bacteria on them?

10 A. Absolutely correct.

11 Q. You've posted other videos showing the same effect?

12 A. A similar effect, yes.

13 Q. Have you ever heard of another medical device,  
14 other than the Bair Hugger, that takes in air from the floor  
15 area and blows it on to a patient?

16 A. There is, I believe, a dressing gown type apparatus  
17 which performs a similar role, the idea of it being to warm  
18 a patient before or after surgery, when they're sitting in  
19 a chair. And I believe that uses similar blower technology  
20 but has a different form of blanket.

21 Q. Is that the Bair Paws?

22 A. I think it may be. I've not used one myself, but  
23 I know of their existence. We discussed yesterday -- sorry,  
24 could you just repeat the question that you asked? Any?

25 Q. There's another medical device that sucks in air



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2 from near the floor area and blows it on to the patient  
3 during a surgery?

4 A. During surgery? No.

5 Q. No?

6 A. Not to my knowledge, no.

7 Q. So, when you were previously discussing the gown  
8 that could be worn, that may have a similar purpose, that's  
9 used in pre and post?

10 A. I don't know how it's used. I don't know if people  
11 would use that during surgery. I don't have any experience  
12 of that. I believe that's compatible with the Bair Hugger  
13 forced-air warming blower units, but I haven't seen it used.  
14 I'm aware of its existence.

15 Q. Isn't the fact that the Bair Hugger is blowing air  
16 on to the patient inimical to the purpose of laminar  
17 airflow?

18 MR. C. GORDON: Object to the form of the  
19 question.

20 A. It potentially compromises what is a very fragile  
21 system. Laminar airflow is far more fragile than, I think,  
22 many people believe, and warm air blowing in the region of  
23 laminar airflow can, in my opinion, disrupt laminar airflow,  
24 especially if the conditions are correct to do it, such as  
25 if laminar airflow is blocked by overhead operating lights

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2 or other equipment, or surgeons, or any other thing in the  
3 way of the laminar airflow.

4 BY MR. SACCHET:

5 Q. And speaking of fragility, the situation is also  
6 very fragile because just us single bacterium could cause  
7 a deep joint infection; correct?

8 A. Correct.

9 Q. So, over a hour-long surgery or more, all it takes  
10 is one bacterium from air disruption, as a result of the  
11 Bair Hugger, to cause a surgical site infection?

12 A. That is possible.

13 Q. Have you seen the recent guidance from the  
14 Healthcare Infection Control Practice Advisory Committee  
15 regarding water heater-cooler devices?

16 A. Regarding?

17 Q. Water heater-cooler devices.

18 A. I have not.

19 Q. So unfortunately I only have two copies of this  
20 document, so Mr. Head and Mr. Gordon can potentially share,  
21 or Mr. Head can share with Mr. McGovern.

22 MR. C. GORDON: Is it about the heater-cooler  
23 units?

24 MR. SACCHET: Yeah.

25 MR. C. GORDON: I don't need that.

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2 (Exhibit 4 marked for identification)

3 MR. SACCHET: If Mr. Head wants one, he is welcome  
4 to it.

5 A. Okay, I see the document. I have not read this, to  
6 my memory.

7 BY MR. SACCHET:

8 Q. Yes. On the first page, you see that the caption  
9 bears "Department of Health and Human Service Centers for  
10 Disease Control and Prevention"; correct?

11 A. Correct.

12 Q. And beneath that is annotation of the Healthcare  
13 Infection and Control Healthcare Advisory Committee  
14 November 5 to 6, 2015, in Atlanta, Georgia?

15 A. Yes.

16 Q. "Record of Proceedings"?

17 A. Yes.

18 Q. If you could turn to page 24.

19 A. Yes.

20 Q. The top of the page states:

21 "Nontuberculosis Mycobacterium Infections  
22 Associated with Heater-Cooler Devices"; correct?

23 A. "Nontuberculosis Mycobacterium Infections  
24 Associated with Heater-Cooler Devices." Yes.

25 Q. You're more qualified to say that. In any case,

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2 beneath that we have two individuals: Joseph Perz, the  
3 leader of Quality Standards and Safety Team, Division of  
4 Healthcare Quality Promotion; and we have Doctor Michael  
5 Bell, Deputy Director, Division of Healthcare Quality  
6 Promotion; correct?

7 A. Correct.

8 Q. And the section leads off with a statement of the  
9 effect:

10 "Dr. Perz reviewed points about  
11 Nontuberculosis Mycobacterium (NTM) and infections  
12 associated with heater-cooler devices"; correct?

13 A. Correct.

14 Q. And the last sentence on that page states --  
15 actually the second-to-the-last sentence and the last  
16 sentence state:

17 "Investigators in a Swiss hospital identified  
18 six cases of invasive M. Chimaera in patients who had  
19 received implants as part of their open-heart cardiac  
20 procedures. The investigation focused on possible  
21 water sources, since the outbreak was of an NTM  
22 infection."

23 Correct?

24 A. Yes.

25 Q. Turning to the next page, second-to-last sentence

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2 states:

3 "Preliminary epidemiologic and laboratory  
4 findings point to the heater-cooler unit as the source  
5 of the NTM."

6 Correct?

7 A. Yes.

8 Q. And turning to the next page, the first full  
9 paragraph begins:

10 "The investigation is public. Even with  
11 preliminary results, there was a sense of urgency that  
12 the findings were important to share, especially with  
13 the patients."

14 And the last sentence of that paragraph says:

15 "The recommendations from FDA include the  
16 following:"

17 The third bullet says:

18 "Direct the exhaust away from the sterile  
19 field."

20 A. Yes.

21 Q. I know you may not be familiar with water  
22 heater-cooler devices, but do you believe that that  
23 recommendation would be well taken, with respect to  
24 forced-air warming devices?

25 MR. C. GORDON: Object to the form of the

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2 question: lack of foundation, incomplete hypothetical,  
3 assumes facts not in evidence.

4 (Reporter clarification.)

5 A. I'm not familiar with this study, this situation,  
6 or these units. I would say that it is well advised to  
7 direct any air exhaust unit from any medical, or any  
8 electronic or electric device, away from a sterile surgical  
9 field.

10 BY MR. SACCHET:

11 Q. And to the extent there's been a objection about  
12 foundation, you performed studies with the respect to the  
13 disruption of laminar flow from the forced-air warming  
14 devices; correct?

15 A. I have.

16 Q. And you've seen the conduction currents that have  
17 been created as a result of the device; correct?

18 A. I have.

19 Q. So, as a result, you would recommend that those  
20 convection currents be directed elsewhere, away from the  
21 surgical site; correct?

22 A. I would.

23 Q. Turning to the next page, at the top, it states:

24 "Dr. Bell said that learning of an event such  
25 as this outbreak presents an opportunity to ensure that

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2 no one else is exposed."

3 A. Yes.

4 Q. And the last paragraph begins:

5 "The heater-cooler unit appears to be  
6 harmless from an infection perspective, but the water  
7 overflow bottle is likely rarely, if ever, sanitized  
8 and is situated in front of a fan."

9 This is the statement I want you to focus on:

10 "Nothing that blows air should be in an  
11 operating room -- theater [I apologize. I said "room"  
12 but it should be "theater"] if possible."

13 A. Yes.

14 Q. The plain language of that statement has nothing to  
15 do with water heater-cooler devices, does it?

16 MR. C. GORDON: Object to the form of the  
17 question: lack of foundation.

18 A. As far as I can tell, this statement refers to  
19 anything blowing air in an operating theater.

20 BY MR. SACCHET:

21 Q. You can read English; correct?

22 A. I can.

23 Q. You have foundation to understand the words written  
24 on the page?

25 A. I can.

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2 Q. And nothing in it says anything about water  
3 heater-cooler devices?

4 A. Nothing in that sentence says anything about water  
5 heater-cooler devices.

6 Q. Do you agree that forced-air warming units should  
7 not be in orthopedic operating procedures?

8 A. It depends. If I were given a choice between no  
9 warming and forced-air warming, I'd choose forced-air  
10 warming, because hypothermia is also a significant problem.  
11 However, ideally, if a patient can be warmed, I would  
12 choose, were I having an operation, to avoid forced-air  
13 warming devices being in an operating room that I was having  
14 an operation in.

15 Q. And there are other warming devices; correct?

16 A. There are other warming devices.

17 Q. So, if there are other warming devices, you  
18 wouldn't need to use forced-air warming?

19 A. If it were my choice and it was my operation, or  
20 I had free rein over the budget of the operating  
21 environment, I would avoid using forced-air warming.

22 MR. SACCHET: Let's take a break.

23 THE VIDEOGRAPHER: This is the end of DVD 1 in  
24 volume 2 of the deposition of Dr. Paul McGovern. We're  
25 going off the record at 10:47.



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2 (10:47 a.m.)

3 (Break taken.)

4 (11:04 a.m.)

5 THE VIDEOGRAPHER: This is the beginning of DVD 2  
6 in volume 1 of the deposition of Dr. Paul McGovern. Back on  
7 the record at four minutes past eleven.

8 BY MR. SACCHET:

9 Q. During the deposition yesterday, you were asked  
10 questions about a microbiology study that you conducted in  
11 approximately 2009; correct?

12 A. Correct.

13 Q. You mentioned yesterday that prior to participating  
14 in the microbiology study, you had very limited experience  
15 with respect to conducting experiments?

16 A. Correct.

17 Q. Your only exposure was in the role of a co-author  
18 on a paper in which you played no part in the experimental  
19 set-up or design; correct?

20 A. That was not an experimental paper; that was one  
21 which looked at using computer software to organize systems.  
22 It was not a directly clinical or experimental paper, and my  
23 involvement in that was to perform a paper-based audit. So  
24 it was not -- my role was not clinically focused. Although  
25 it had clinical relevance, it was not really a clinical

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2 paper.

3 Q. It would be fair to say that the microbiology study  
4 in 2009 was the first study in which you were involved in  
5 designing, setting up and conducting an experiment; correct?

6 A. That is correct.

7 Q. And it was, as a result, the first study in which  
8 you examined forced-air warming devices; correct?

9 A. Correct.

10 Q. And at that point in time you had taken a course in  
11 microbiology but you certainly had not conducted  
12 microbiological experiment before?

13 A. That's correct.

14 Q. This was before the time in which you collaborated  
15 with Mr. Mark Albrecht; correct?

16 A. Yes, yes.

17 Q. Mr. Albrecht was not involved in this study;  
18 correct?

19 A. Not to my recollection, no.

20 Q. So, as of August 2009, you had very limited  
21 experience in designing and conducting studies of this sort?

22 A. That's correct.

23 Q. And as you mentioned yesterday, as a result of  
24 that, you had little idea as to how to set up a proper  
25 methodologically sound experiment; correct?

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2 A. Correct.

3 Q. You played some role, however, in designing the  
4 protocol for the experiment; correct?

5 A. Yes.

6 Q. You were asked by Mr. Reed to submit a protocol to  
7 him and others that would be involved in the experiment;  
8 correct?

9 A. Correct.

10 Q. That protocol -- in that protocol, did you  
11 collaborate with an individual named Tom Symes, or was it  
12 purely your product?

13 A. I did collaborate with an individual called Tom  
14 Symes. He, from my memory, was vaguely involved in it. I  
15 may -- he, at the time, was a very senior trainee about to  
16 become an attending level surgeon within a year, I think, of  
17 that period of time -- maybe two. I remember that he was  
18 working in my department. I may have discussed potential  
19 designs with him, but to my recollection, the vast majority  
20 of the work in designing the protocols, or the study design  
21 for that experiment, was mine.

22 (Exhibit 5 marked for identification)

23 A. Thank you.

24 Q. Is the document before you a draft protocol that  
25 you helped write and design?

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2 A. Yes.

3 Q. Does experiment 1, which states:

4 "Set up a Bair Hugger device in simulated  
5 intra-operative conditions with sampling air from  
6 surgical field to culture distributed bacteria."

7 A. Yes.

8 Q. Is that likely the microbiology study that was  
9 conducted?

10 A. That is likely the microbiology study that was  
11 conducted, or a draft of the proposal. Not having read  
12 through this, I don't know if it exactly correlates to it,  
13 but this is what I was referring to in experiment 1. It is  
14 the same study.

15 Q. There appears to be comments from Mike Reed in the  
16 right-hand column; correct?

17 A. Correct.

18 Q. And there are also appears to be comments stated in  
19 capital letters in the text of the document; correct?

20 A. Correct.

21 Q. Are those comments in capital letters from  
22 Professor Leaper?

23 A. I do not recall.

24 Q. In any case, the first comment under "Experiment 1"  
25 following the first sentence, says:

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2 "It will be important to state which FAW  
3 unit/model (750? 550?) you are using and if it is in  
4 current use (i.e. contaminated) or new ..."

5 A. Yes, it says that.

6 Q. Do you recall which model device you used in  
7 conducting the microbiology study?

8 A. I do not.

9 Q. So we'll have to toggle back and forth between  
10 these two documents.

11 (Exhibit 6 marked for identification)

12 A. Thank you.

13 Q. Is this document the draft of the microbiology  
14 study?

15 A. It is.

16 Q. On the second, or I guess the third page under the  
17 heading entitled "Methods", do you see in the first  
18 paragraph the notation of use of "Bair Hugger Model 505,  
19 Arizant Healthcare, USA"?

20 A. I do.

21 Q. Does that refresh your recollection that a model  
22 505 Bair Hugger was used in the microbiology study?

23 A. It does.

24 Q. At the time you conducted this study, you were  
25 aware of the fact that the 505 was a less powerful device

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2 than the 750; correct?

3 A. I don't know if I was aware of that at that time.  
4 I think it's likely I was aware of that, because it's  
5 physically smaller and older, and looks it, and I'm  
6 certainly aware of that now.

7 Q. Would it refresh your recollection if I showed you  
8 a document from an approximate time period similar to the  
9 one in which the study was designed in which you made  
10 statements to that effect?

11 A. It doesn't surprise me that I would have made that  
12 statement, and it would refresh my recollection, yeah.

13 (Exhibit 7 marked for identification)

14 A. Thank you.

15 Q. If you could turn to the very last page, which  
16 would be 14 of 14 of this e-mail thread. In the middle of  
17 the page, do you see an e-mail dated November 11, 2009, from  
18 you to Mike Reed?

19 A. Yes.

20 Q. And in this e-mail, you state:

21 "Models of Bair Huggers are 505 -- the one  
22 most commonly used in theater. There is also the 750  
23 which is bigger, and powerful enough to power a whole  
24 body warming blanket. The 505 is for half body."

25 A. Yes.

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2 Q. You then continue to state:

3 "I don't think they have records of which  
4 were used for which patient, though could look into  
5 this -- be interesting if the use of the big powerful  
6 one has been used in lots of cases that eventually got  
7 infected."

8 A. Yes.

9 Q. Does that refresh your recollection that around the  
10 time in which this study was conducted, you were aware that  
11 a 505 was less powerful than a model 750?

12 A. It does.

13 Q. If the 750 is more powerful than a 505, would it  
14 generate more excess heat in the operating room environment?

15 MR. C. GORDON: Object to the form of the  
16 question: lack of foundation, incomplete hypothetical.

17 A. It's possible. It would depend on where the power  
18 went -- if the power was in the blower unit, or the heater  
19 unit, or both. Because I don't know the precise design of  
20 each, I can't comment on the likely power output into the  
21 operating room.

22 BY MR. SACCHET:

23 Q. You had an interest in whether the 750 had been  
24 linked to infections; correct?

25 A. Correct.

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2 Q. And you stated that in the document to Mr. -- in  
3 the e-mail to Mr. Mike Reed; correct?

4 A. Correct.

5 Q. Were you aware, at the time of this study, that the  
6 model 505 had different filtration than the model 750?

7 A. Not to my recollection.

8 Q. You're aware of that now?

9 A. Yes.

10 Q. You only tested the model 505; correct?

11 A. I believe so.

12 Q. So the 700 was never tested -- the 750 was never  
13 tested?

14 A. For this experiment, I do not believe the 750 was  
15 used at all.

16 Q. In the past, you have said that the model 505 is  
17 obsolete. Do you recall making that statement?

18 A. I don't directly recall it, but think it was being  
19 superseded and that, to my recollection, the 505s were  
20 replaced gradually by 750s and so were made obsolete, yes.

21 Q. Even if the results of this study had statistical  
22 significance, which you said yesterday that it did not, it  
23 would have no relevance whatsoever to the model 750 or 775,  
24 would it?

25 MR. C. GORDON: Object to the form of the



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2 question.

3 BY MR. SACCHET:

4 Q. Let me back up. The model 750 is a different model  
5 than the 505; correct?

6 A. That is correct. They're different models.

7 Q. You know that it has different filtration than the  
8 505?

9 A. Correct.

10 Q. And in the prior emails, you stated that the 750  
11 had greater airflow than the 505?

12 A. I said that, yes.

13 Q. Would it be reasonable to assume, based on those  
14 facts, that the results of this study, which involved the  
15 505, would not relate directly to the model 750 Bair Hugger,  
16 based on those differences?

17 A. It's possible that results, whether positive or  
18 negative, could correlate between the two, because there are  
19 two possible mechanisms for bacteria getting into settle  
20 plates, or into the bacterial detection unit that were used.  
21 One could be that bacteria were drawn directly from the  
22 blower unit to the patient, but another is that bacteria  
23 could have been drawn from the patient because of the  
24 airflow to the sterile field. The mechanism of bacteria  
25 transfer from the patient's own skin, or from a surgeon, or

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2 from another person, to the operative field, may not have  
3 been affected. And were that the origin of any bacteria,  
4 then that would have been applicable to both models; but any  
5 conclusions that could be drawn about whether the model 505  
6 was blowing air from itself into an operative field could  
7 not, in my opinion, be applicable to the 750.

8 Q. So, with respect to particles that may enter the  
9 surgical field as a result of the Bair Hugger, the results  
10 from the 505 may not translate to the 750?

11 A. Results of bacteria which started in the blower  
12 unit getting to the operative site may not be applicable  
13 between investigations involving two different types of  
14 units, in my opinion.

15 Q. If we go back to the protocol, there was a  
16 statement which I had read before, which said -- and  
17 questioned whether you would be using used or a new devices?

18 A. Yes.

19 Q. Do you recall whether you used used or new devices  
20 in this study?

21 A. I do not recall whether used or new devices were  
22 used in this study.

23 Q. If you had used new devices, would you be surprised  
24 by the fact that the air which came out of the hose resulted  
25 in no bacteria?

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2 A. I would not be surprised by that. I would expect  
3 a new device to have zero bacteria when sampling the air  
4 directly from the outlet.

5 Q. Going back to the protocol, at the bottom of the  
6 page in the third-to-the-last bullet point.

7 A. Which exhibit are we on?

8 Q. This is exhibit 5.

9 A. Last page, bottom?

10 Q. First page, bottom.

11 A. Yes.

12 Q. The third-to-last bullet point, which is kind of  
13 a sub-bullet point of sorts, says, "Use Ioban"?

14 A. Yes.

15 Q. Are Ioban drapes the same as in-size adhesive  
16 drapes?

17 A. I don't know exactly what an in-size drape is, but  
18 an Ioban drape is a thin plastic membrane with adhesive on  
19 one side, and impregnate with iodine. The idea is that that  
20 drape is slightly thicker than saran wrap -- or what we  
21 would call clingfilm -- and sticks to the patient. And when  
22 the incision is made, the incision is made through that  
23 substance, through that plastic sheet; and the edges of the  
24 wound remain adherent to the plastic, the idea being that  
25 bacteria from the skin are less likely to migrate into the

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2 wound. It is not clear to me whether they are actually  
3 effective, and whether they actually reduce infection rates,  
4 but that is the principle behind that equipment.

5 Q. Do you recall whether the Ioban drape you used in  
6 this experiment was manufactured by 3M?

7 A. To my recollection, we did not use an Ioban drape  
8 in this experiment.

9 Q. You did not?

10 A. To my -- in the actual experiment, Ioban was not  
11 used. I think, from looking at the image yesterday of that  
12 experiment, or photographs that were taken at the time,  
13 there was certainly no Ioban drape on that. I don't  
14 remember if it is mentioned in the methods, but this was  
15 a plan. And this, the methods discuss -- discusses what was  
16 actually done.

17 Q. Fair enough.

18 A. I don't think an Ioban drape was used.

19 Q. With respect to the blanket itself, you did not use  
20 what is known as an underbody blanket; correct?

21 A. Correct. It was an overbody blanket.

22 Q. Do you know what an underbody blanket is?

23 A. Yes. Although I was not aware that there was an  
24 underbody blanket available as a Bair Hugger.

25 Q. Are you aware that 3M now manufactures an underbody

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2 blanket?

3 A. I was not aware of that.

4 Q. Are you aware of whether underbody blankets use  
5 drapes?

6 A. Use drapes?

7 Q. Are drapes used in combination with underbody  
8 blankets when surgeries are performed?

9 A. I have no experience of using underbody blankets,  
10 but I can't envisage a situation in which surgical drapes  
11 would not be used if an underbody blanket was used as well.  
12 Surgical drapes are necessary to maintain a sterile field,  
13 and I cannot imagine a situation in which the drapes would  
14 not be used in surgery of this type.

15 Q. So, in a moment you'll receive a document, and I'm  
16 going to ask you to turn to the last page of the document,  
17 even though the preceding pages are the study you  
18 co-authored with Mr. Mike Reed involving the design of  
19 forced-air warming devices.

20 (Exhibit 8 marked for identification)

21 MR. C. GORDON: Which page are you?

22 MR. SACCHET: Last page.

23 MR. C. GORDON: What's the Bates number?

24 BY MR. SACCHET:

25 Q. One moment. Do you see the Bates number in the

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2 bottom right-hand corner labeled 3MBH00107870?

3 A. I do.

4 Q. Do you see a picture of an individual on an OR  
5 stand with a blanket underneath the individual?

6 A. I do.

7 Q. Do you see the designation on the right-hand side  
8 of the page which says, "Underbody series", and six  
9 different underbody blankets are pictured therein?

10 A. I do.

11 Q. The text of the document states: "Warm from Below."

12 A. It does.

13 Q. "The 3M Bair Hugger underbody blanket series offers  
14 warming for virtually any surgery, routine to complex,  
15 without the risk of heating pressure points. Our seven  
16 underbody series blankets deliver all the benefits of  
17 forced-air warming with the convenience of unrestricted  
18 patient access and smart design features like unique surface  
19 outlets that prevent fluid pooling."

20 A. Yes.

21 Q. Do you see, in this picture, any drapes on the  
22 patient?

23 A. I do. There appears to be a plastic drape over the  
24 head end of the patient, but not a surgical drape as I would  
25 recognize it.

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2 Q. If this were performed in "virtually any surgery",  
3 as the document states, there are certainly areas of the  
4 body on this picture that could be operated on, but would  
5 not have draping around the area; correct?

6 A. Sorry, I don't understand.

7 Q. Sure. So, if this individual were to have a TKA,  
8 total knee arthroplasty?

9 A. Right.

10 Q. There is no indication that draping would be over  
11 the opposite leg, or the torso, or the breast area of this  
12 individual; correct?

13 A. You mean surgical draping? In this picture?

14 Q. Yeah. Does there appear to be any draping over  
15 other areas of --

16 A. There is no draping in that picture, that I can  
17 see, that is consistent with an operation. There is no  
18 sterile surgical draping I can see, no.

19 Q. And the text states "For unrestricted patient  
20 access"; correct?

21 A. It does.

22 Q. Assuming that drapes are not used with this  
23 particular style of blanket ...

24 A. Right.

25 Q. ... would the results of your microbiology study

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2 have any impact on the use of this kind of blanket?

3 A. I have no idea.

4 MR. C. GORDON: Object to the form of the  
5 question: lack of foundation, assumes facts not in evidence,  
6 calls for speculation.

7 A. I have no idea.

8 BY MR. SACCHET:

9 Q. Would you be concerned if -- as an orthopedic  
10 surgeon, would you concerned, during your training, if  
11 draping was not used in a blanket that was underneath a  
12 patient that blew air upward toward the patient?

13 A. I'd be concerned if draping wasn't used in an  
14 operation.

15 Q. Okay. Why?

16 A. Because, in an arthroplasty procedure, draping is  
17 essential to isolate the sterile surgical field and minimize  
18 the possibility of infection.

19 Q. So, if draping were not used, it may allow  
20 particles or bacteria to enter the surgical site that  
21 draping would otherwise prevent?

22 MR. C. GORDON: Same objections.

23 A. If draping were not used in an operation, then -- I  
24 mean, it's inconceivable that draping wouldn't be used in an  
25 arthroplasty operation, as far as I'm concerned, but if



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2 draping were not used, then the -- there would be a  
3 significantly higher chance of infection in any surgical  
4 set-up, with any equipment.

5 BY MR. SACCHET:

6 Q. Okay. Let's go back to exhibit 5, which is the  
7 protocol.

8 A. Yes.

9 Q. Don't worry about that. Exhibit 5.

10 A. Yes.

11 Q. The second-to-last and last bullet points state  
12 that:

13 "Bacteria sampler set up in standardised  
14 position next to 'operative field'."

15 A. Yes.

16 Q. "Casella hose near 'operative field', sampling unit  
17 to be outside laminar flow zone if possible."

18 A. Yes.

19 Q. Were you concerned at any time, during the study or  
20 afterward, about the position of the bacterial sampler in  
21 this study?

22 A. In the study as it was performed, yes, the  
23 bacterial sampler position, in my opinion, was not ideal.  
24 It was probably in the order of a foot away from the  
25 operative field itself. Ideally, it would have been very

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2 close to the operative field, within an inch of it, but it  
3 was not possible with the design of sampler we eventually  
4 used. The Casella sampler, which is mentioned in the plan,  
5 was not available to us.

6 Q. The table in which the sampling unit was placed on  
7 had the potential to block dirty air from rising upward;  
8 correct?

9 A. Were airflow -- yeah, the table upon which the  
10 bacterial sampling unit was placed did, in my opinion, have  
11 the potential to disrupt airflow, whether from above or  
12 below.

13 Q. And the position of the table was certainly not  
14 a realistic set-up of a normal OR environment; correct?

15 A. The position --

16 MR. C. GORDON: Object to the form.

17 A. -- of the table upon which the bacterial sampler  
18 was, yes, was not representative of an OR environment,  
19 because where the table was was where a surgeon would stand,  
20 usually.

21 BY MR. SACCHET:

22 Q. If you had to redo the experiment in order to  
23 determine particle and bacterial counts from the use of the  
24 Bair Hugger model 505, would you have put the table in the  
25 same place?

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2 A. I would use a different piece of equipment  
3 entirely, if I could redo the experiment. I would not use  
4 the equipment that was used.

5 THE VIDEOGRAPHER: Sorry, someone is flicking a  
6 biro or something into the microphones, and it is going  
7 "click click".

8 MR. C. GORDON: Sorry.

9 BY MR. SACCHET:

10 Q. The other way in which you attempted to test the  
11 presence of bacteria was through settle plates; correct?

12 A. Correct.

13 Q. You're aware of the fact that settle plates have  
14 a very low chance of finding particles or bacteria on the  
15 plates; correct?

16 MR. C. GORDON: Object to the form of the  
17 question.

18 A. Well, yeah, they have -- I don't know what the  
19 statistical likelihood of a bacteria landing on a plate in  
20 a colony-forming unit producing a result is. I don't know  
21 what the size of the bacterial load needs to be, for  
22 a positive result on a settle plate. You'd need to ask a  
23 microbiologist that.

24 BY MR. SACCHET:

25 Q. But you testified yesterday that there was a lower

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2 chance of finding bacteria on a settle plate?

3 A. In the experiment that we used, yes, I believed at  
4 the time that it was a low chance of finding bacteria.

5 Q. There were no settle plates placed directly on top  
6 of the wound site; correct?

7 A. Of the -- the simulated operative site, that's  
8 correct. There were no bacteria settle plates placed on  
9 that area.

10 Q. You only had bacterial plates in the vicinity of  
11 the laminar flow boundary; correct?

12 A. They were outside the laminar flow boundary, or  
13 they were within the laminar flow boundary approximately at  
14 the corners of the operating table.

15 Q. And because those plates were at the corners of the  
16 operating table, you could not conclude whether there was  
17 increased bacteria at the surgical site itself?

18 A. That's correct. I could not conclude from the  
19 design of that study, or from that study, whether there were  
20 bacteria at the surgical site.

21 Q. On the next page of the protocol, which is  
22 exhibit 5, in the third bullet, you state:

23 "Particle counts taken (using handheld laser  
24 particle counter) from various positions around  
25 patient."

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2 A. Yes.

3 Q. Do you recall what type of particle counter you  
4 used in the actual study?

5 A. Handilaz Mini.

6 Q. Do you recall any of the potential authors of this  
7 experiment, even though it was never published, to have  
8 expressed concern about the use of that particular type of  
9 particle counter?

10 A. No.

11 (Exhibit 9 marked for identification)

12 Q. Exhibit 9 is a document entitled "Do Forced Air  
13 Warming Devices Increase Bacterial Contamination of  
14 Operative Field?"

15 Do you recognize this document, Mr. McGovern?

16 A. I do.

17 Q. Do you see, on the third page of the document under  
18 the section entitled "Methods", there are comments from  
19 someone bearing the acronym "PS1"?

20 A. I do.

21 Q. Does "PS1" correspond to Sutaria P, named in the  
22 caption of this draft --

23 A. I believe so, yes.

24 Q. Who is Sutaria P?

25 A. Dr. Sutaria is a doctor who said was slightly

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2 junior to me at Wansbeck Hospital, working in the orthopedic  
3 department, who collaborated in the experimental phase, or  
4 collaborated in all phases of this study.

5 Q. Do you see comment "PS3" that states:

6 "Is there any info about the sensitivity of  
7 the device? I.e. size of particles it can pick up and  
8 relevance to pathogenicity?"

9 A. I do see that, yes.

10 Q. Are you aware of the fact that the Handilaz  
11 handheld particle counter was only able to detect particles  
12 sized 0.3, 0.5 and 5 microns?

13 A. Yes.

14 Q. As a result, there was no way that the particle  
15 counter you used in this study would have detected particles  
16 of size 0.2 microns?

17 A. It's impossible to say if it would pick up any  
18 particles of 0.2 microns. You'd have to ask an expert on  
19 that particular machine. The way these machines work is  
20 they have a laser array, and they draw air over the laser  
21 array, and it measures light bouncing off particles, and it  
22 calculates a probability that that number of particles has  
23 been produced. So, if it detects ten particles at  
24 0.5 microns, it doesn't necessarily mean that there are  
25 exactly ten particles; it means it has detected the number

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2 of light scatterings that there are which correspond to  
3 a likely particle size of that. Therefore, it's possible  
4 that it can -- it will register a result for smaller  
5 particles, but I don't know, and you'd have to ask an expert  
6 on that to confirm or refute that.

7 Q. You don't doubt, do you, that the preliminary  
8 results of this experiment only tracked particles of 0.3,  
9 0.5 and 5 microns in size?

10 A. I don't doubt that the machine was designed do  
11 that, and that is the -- those are the results that it  
12 outputted, and that is the best information that we had,  
13 based on the experimental procedure that we used.

14 Q. So there were no results in this study about  
15 particles smaller than 0.3, between 0.3 and 0.4, and between  
16 0.4 and 5, and greater than 5 microns in size?

17 A. Exactly right. That is correct.

18 Q. You're aware of the fact that the most penetrating  
19 particle size of Bair Hugger filters is 0.2 microns?

20 A. I was not aware of that. I may have been, at some  
21 point, but I didn't remember that immediately now.

22 Q. Does it refresh your recollection, upon hearing  
23 that that might be the case?

24 A. It sounds familiar, but I don't remember --  
25 remembering specific particle sizes in filtration rates is

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2 not something I make attempts to do.

3 Q. Okay, check out exhibit 8. The second page of this  
4 document has a title of "Forced-Air Warming Design:  
5 Evaluation of Intake Filtration, Internal Microbial Buildup,  
6 and Airborne Contamination Emissions"; correct?

7 A. Yes.

8 Q. It was authored by Mr. Reed, yourself, and two  
9 other individuals; correct?

10 A. That's correct.

11 Q. On the third page of the document, bearing the  
12 internal pagination 277, there is a table on the top;  
13 correct?

14 A. Yes.

15 Q. And the Figure 1 stands for "Mean Retention  
16 Efficiencies"; correct?

17 A. Yes.

18 Q. The lowest retention efficiency demarcated in this  
19 graph is 0.2 microns in diameter; correct?

20 A. This is a log scale. It's difficult to, because of  
21 the copy, to say with absolute certainty, but --

22 Q. If you count the intervals, you'll be able to tell  
23 there are corresponding increments in 0.1 intervals adding  
24 up to 1 micron in total; correct?

25 A. There are corresponding intervals going up to 0.1,



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2 and the lowest retention efficiency is between 0.1 and 1, on  
3 the log scale, and closer to 0.1. But my copy does not show  
4 the ticks clearly, so although it looks like it is 0.2,  
5 I can't --

6 Q. Sure.

7 A. You'd need a better copy to confirm that.

8 Q. Beneath the Figure 1 do you see the section bearing  
9 the name "Results"?

10 A. Yes.

11 Q. And it states:

12 "Intake Filter Retention Efficiency."

13 A. Yes.

14 Q. "The mean efficiency for intake filter model  
15 750093D (n=5) was found to be 63.8% [efficient] at the MPPS  
16 of 0.2-micron."

17 Do you see that?

18 A. Yes.

19 Q. What does "MPPS" stand for?

20 A. I --

21 Q. Does "most penetrating particle size" ring a bell?

22 A. It does, but I'd have to -- there should be a  
23 definition earlier in the paper of the abbreviation.

24 Q. If you look at the second page of the study, in the  
25 first full paragraph beginning "Filtration efficiency"?

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2 A. Yes.

3 Q. The last sentence says --

4 A. Yeah --

5 Q. "The most penetrating particle size (MPPS) is  
6 defined as the particle size at which the filter displayed  
7 the minimum efficiency."

8 Do you see that?

9 A. Yes, I do see that, and that's what I understand by  
10 MPPS, yes.

11 Q. Would you agree that, based on the text of the  
12 study in which you co-authored, that the MPPS of this model  
13 filter of the Bair Hugger is 0.2-micron?

14 A. Yes, that is what the study says.

15 Q. So, to be clear, the results of the microbiology  
16 study conducted in 2009 did not report directly on the most  
17 penetrating particle size of that particular Bair Hugger  
18 filter?

19 A. That is correct, in my opinion.

20 Q. Would it also be fair to say that the output of  
21 counted particles from the Handilaz particle counter "do not  
22 represent a true count of undivided particles"?

23 MR. C. GORDON: Object to the form of the  
24 question.

25 MR. SACCHET: What's the basis of the form of the

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2 objection?

3 MR. C. GORDON: Vague and -- basically using  
4 terminology that doesn't have any intrinsic meaning.

5 MR. SACCHET: Okay, well, we can get through that.

6 A. Repeat the question, please?

7 BY MR. SACCHET:

8 Q. Would it be fair to say that the output of counted  
9 particles from the Handilaz particle counter do not  
10 represent a true count of undivided particles?

11 A. Well, my understanding of the way that particle  
12 counter works, the results to outputs are approximations and  
13 extrapolations of laser defractions, and therefore may or  
14 may not represent true absolute values of the number of  
15 particles in the detection chamber at that time. However,  
16 that would be better answered by someone who has specific  
17 training and understanding of that device.

18 Q. So, in other words, particle counters express  
19 numerical values of counted particles of varying size, but  
20 due to the technique of counting, the output does not  
21 represent a true count of individual particles?

22 MR. C. GORDON: Object to the form. Also, lack of  
23 foundation.

24 A. Yes, in my opinion.

25 BY MR. SACCHET:

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2 Q. I could cure the foundation by showing you  
3 a document, but I'm not going to.

4 Moving on to the protocol, exhibit 5.

5 A. Yes.

6 Q. Under the section bearing the title "Experiment".

7 A. Yes.

8 Q. Does it state that the experiment was performed for  
9 30 minutes in duration?

10 A. Sorry, in exhibit 5?

11 Q. Under the heading entitled -- Oh, on the second  
12 page under the heading entitled "Experiment".

13 A. Yes. This doesn't say it was. It says this was  
14 the plan. I think, in reality, it was performed for 30  
15 minutes, but this document doesn't say that.

16 Q. Yes. And it then goes on to say that:

17 "10 minutes fully set up with Bair offered to act  
18 as control.

19 "10 minutes with Bair Hugger on

20 "10 minutes with equipment turned off."

21 Correct?

22 A. Yes.

23 Q. Why use 10-minute increments for particle counting?

24 A. To allow sufficient time for systems to equilibrate  
25 to reduce the chance of a single movement, say a cough or

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2 a door opening, or any unpredictable event, significantly  
3 affecting any data that we collected. The idea behind that  
4 was ten minutes, chosen arbitrarily, was a long enough  
5 period of time to smooth out any unexpected spikes of  
6 particles.

7 Q. So the 10-minute period was used to cure any spikes  
8 in particles, but you would agree that 10 minutes is not the  
9 normal time for an orthopedic surgery; correct?

10 A. I would very much agree that that is a -- very much  
11 shorter than most orthopedic surgeries.

12 Q. Do you recall that bacterial samples were only  
13 collected for five minutes?

14 A. I don't recall exactly how long they were collected  
15 for. I imagine it is in the methods of that write-up.

16 Q. Yeah, do you want to turn back to that? Exhibit 6.

17 A. Yes.

18 Q. On the third page of the document, in the "Methods"  
19 section, in the third-to-last paragraph, it says: "Samples  
20 were collected for five minutes." Do you see that?

21 A. Which paragraph, sorry?

22 Q. Third-to-last paragraph.

23 A. Yeah, yes. Same.

24 Q. That's vastly shorter than a typical orthopedic  
25 surgery; correct?

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2 A. I agree that's --

3 MR. C. GORDON: Object to the form of the  
4 question.

5 A. I agree, that's significantly shorter than the  
6 typical orthopedic surgery.

7 BY MR. SACCHET:

8 Q. How much shorter?

9 A. Depends on the operation. For hip or knee  
10 arthroplasty, I would expect operation time in the order of  
11 an hour, but could be 90 minutes, could be 2 hours. No  
12 shorter, in general, than 40 minutes to half an hour -- 40  
13 minutes. But that would be exceptional.

14 Q. If you had increased the duration of the testing  
15 from 10 minutes to a longer period, or 5 minutes to a longer  
16 period, might you have seen increased particles of bacteria?

17 MR. C. GORDON: Object to the form of the  
18 question. Calls for speculation.

19 A. I've no idea.

20 BY MR. SACCHET:

21 Q. In other studies that you drafted protocols for,  
22 you used longer testing periods; correct?

23 A. Correct.

24 Q. More than -- equal to, or more than, 20 minutes?

25 A. Over various different experimental runs, I'd have

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2 to look at the specific protocols, but the total testing  
3 time was, as far as I can remember, longer than for this  
4 study.

5 Q. Why did you have longer testing periods in other  
6 studies?

7 A. They were longer, or more -- a longer total period  
8 of testing to provide a greater quantity of results, and  
9 because those studies were designed from the outset to  
10 provide data that could be analyzed statistically.

11 Q. So, with a longer time period, you would naturally  
12 accumulate more data?

13 A. That would generally be what I would expect for  
14 this type of study.

15 (Reporter clarification.)

16 Q. And with more data, there is a greater likelihood  
17 of better powering of the study?

18 MR. C. GORDON: Object to the form of the  
19 question.

20 A. Not -- there's not a direct correlation. The study  
21 needs to be designed appropriately, according to what it is  
22 showing. More data is not necessarily better, because data  
23 can be flawed and can be useless. So collecting more -- it  
24 is quality not quantity. For these types of studies,  
25 a longer period of time collecting data may be helpful, but

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2 if the study is well designed, then a shorter period of time  
3 could be useful. It really depends on the specific design  
4 of the study and what it's trying to test.

5 BY MR. SACCHET:

6 Q. On a related note, do you recall that only four  
7 runs were conducted in this study; correct?

8 A. Yes, that's right.

9 Q. Three of those runs were the exact same, in which  
10 the Bair Hugger was off and then the Bair Hugger was on, and  
11 then the surgeon entered the room, and one of them, of the  
12 four runs, involved the surgeon tracing his or her hand over  
13 the wound site with a glove?

14 A. Yes.

15 Q. So, in effect, there were really only three runs  
16 that were exactly the same?

17 A. I don't remember if the three runs were identical  
18 to each other, and if one was different, then -- I'll have  
19 to go and check the methods. Yes, that is correct. So what  
20 I've said here is the method was repeated for four  
21 experiments, but the implication is that three experiments  
22 were the same, and experiment 4 was a variation of that, in  
23 that the surgeon continually drew their gloved hand over the  
24 skin of the operative field throughout the sampling period.

25 So yes, three experiments were repeat -- well, were



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2 the same, and experiment 4 was variant to the others.

3 Q. Three runs isn't a lot, is it?

4 MR. C. GORDON: Object to the form of the  
5 question.

6 A. No.

7 BY MR. SACCHET:

8 Q. The original proposal for this study called for  
9 a minimum of ten runs; do you recall that?

10 A. I didn't recall that. I can look at it.

11 Q. Not the one before you, but do you ever recall  
12 learning that ten runs were supposed to be performed?

13 A. I don't remember --

14 MR. C. GORDON: Object to the form of the  
15 question.

16 A. -- that being mentioned. It may well have been,  
17 but I'd need to check a document to verify that.

18 BY MR. SACCHET:

19 Q. Do you recall intending to perform ten runs?

20 A. I do not.

21 (Exhibit 10 marked for identification)

22 Q. This is an e-mail thread among you, Ms. Val  
23 Edwards-Jones, or rather Professor Edwards-Jones, and  
24 yourself; correct?

25 A. Correct. And I have said that we will hopefully

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2 get up to ten cycles completed.

3 Q. So your intention, or your hope, was to run at  
4 least ten runs of this experiment?

5 A. That's correct.

6 Q. Moreover you considered performing additional runs  
7 after the initial results came in; correct?

8 A. I don't remember.

9 (Exhibit 11 marked for identification)

10 Q. Let's go to -- I believe it's the last page, if  
11 memory serves. Yes.

12 A. I did consider doing additional runs after the  
13 first set of experiments were completed.

14 Q. That's what you told your colleague, Mr. Sprowson?

15 A. Yes.

16 Q. You never performed additional runs, did you?

17 A. No.

18 Q. Based on the fact that you never performed  
19 additional runs, and only three runs were actually performed  
20 when you intended to perform ten runs, were you happy with  
21 the number of runs that were actually performed in this  
22 study?

23 A. No.

24 Q. Since you never performed additional runs in this  
25 study, you would agree that you cannot evaluate the

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2 statistical significance of the data presented in this  
3 manuscript; correct?

4 A. Since there weren't that many runs, and because the  
5 study was not designed to allow for statistical analysis.  
6 It may have been possible with more runs, but the whole  
7 premise of the study did not lend itself to further  
8 analysis.

9 Q. There's nothing in this study that is statistically  
10 significant?

11 A. Nothing was found in this study which was  
12 statistically significant; that is correct.

13 Q. You never planned, with a statistician, to design  
14 this study?

15 A. That's correct.

16 Q. You never had Mr. Albrecht's expertise to  
17 appropriately design this study to be adequately powered?

18 A. That is correct.

19 Q. This study wasn't even conceived to produce  
20 statistically powered results?

21 A. Correct.

22 Q. The study wasn't even randomized, was it?

23 A. I don't believe so, no.

24 Q. You're certain of that?

25 A. There was no -- there was nothing to randomize.

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2 There were three sequential experiments which were the same,  
3 and another one which was done as a variation to that  
4 experiment. So there was nothing random about that. So no,  
5 it wasn't. It wasn't randomized.

6 Q. And because it wasn't randomized, and because there  
7 weren't enough runs in the study, you wouldn't be able to  
8 determine a P value for the data; correct?

9 MR. C. GORDON: Object to the form of the  
10 question.

11 A. I don't know if not being able to determine a P  
12 value is a direct consequence of not randomizing the  
13 experimental runs, but in this case, as far as I'm aware, a  
14 P value can't be derived from this data. It may be that  
15 a statistician could derive something, but it is not  
16 something I've ever attempted to do, and not something that  
17 I believe was worth pursuing.

18 BY MR. SACCHET:

19 Q. Because this study did not lend itself to  
20 statistically significant results, you said yesterday that  
21 this is not a good study. Do you stand by that statement?

22 A. I stand by it. I do not believe this is a good  
23 study.

24 Q. You would also hope to use a Casella bacterial  
25 sampler in this study; correct?

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2 A. Were nothing else changed, I'd want to use  
3 a Casella. But I would want to change quite lot about the  
4 design of the study, but a Casella would be preferable than  
5 the equipment that was used.

6 Q. A Casella is similar to a slit sampler?

7 A. I believe so. It is a bacterial sampler which  
8 draws air from a small hose unit which goes near the area to  
9 be sampled, as far as I'm aware.

10 Q. Was the sampler that you used, which is called  
11 a Sarstedt sampler, that was noted in the method section of  
12 the manuscript, was that the sampler that was provided to  
13 you at the time by NHS?

14 A. Yes, I believe so.

15 Q. Do you recall learning that if you used that  
16 sampler, the data would not be of a high enough standard to  
17 produce publishable data?

18 A. I was not aware of that when I was using it.

19 Q. Do you recall learning that?

20 A. I do not.

21 Q. If you could go back to exhibit 11.

22 A. Yes.

23 Q. Do you see, on page 4 of 11, an e-mail dated  
24 13th September 2009, from you to Mr. Reed?

25 A. Yes.

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2 Q. The e-mail states:

3 "Mr. Reed spoke to Dr. Oswald on Friday but  
4 she was snowed under and couldn't give me more than  
5 a couple of minutes. I'm booked for a proper meeting  
6 with her in the coming week."

7 Who is Dr. Oswald?

8 A. I think she was a microbiologist working at the  
9 Hospital Trust at the time, but I would need to check.

10 Q. Fair enough, but she was a doctor; correct?

11 A. Yes.

12 Q. You then state:

13 "We did discuss the slit sampler and she said  
14 the one the department has is not ideal for the task,  
15 and may not be of a high enough standard to produce  
16 publishable data."

17 Do you see that?

18 A. I do see that.

19 Q. So at one point in time, specifically September 13,  
20 2009, you were advised of the fact that the sampler that you  
21 used in this study may not lend itself to publishable data?

22 A. It may not have done.

23 Q. Yeah. It may not.

24 A. It may not have done. That was what I learned at  
25 the time.

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2 Q. And you never used the Casella sampler; is that  
3 correct?

4 A. I've never used a Casella sampler. I've seen  
5 pictures of one, but I've never used one.

6 Q. As a result of not using the Casella sampler or  
7 a slit sampler, did you tell Mr. Reed that:

8 "The experiment suffered from having to make up the  
9 bacterial side of things on the day. A Casella or  
10 similar might yet have shown the bacterial contamination  
11 we were looking for"?

12 A. I don't remember saying that. Perhaps you could  
13 direct me to where I have?

14 Q. It's not in there.

15 (Exhibit 12 marked for identification)

16 A. Thank you.

17 Q. Do you see, at the top of the page, an e-mail from  
18 you to Mr. Reed dated February 21, 2010?

19 A. Yes.

20 Q. The last sentence of the second paragraph states:

21 "I think the Bair Hugger thing suffered  
22 a little from having to make up the bacterial side of  
23 things on the day -- a casella or similar might yet  
24 have shown the bacterial contamination we were looking  
25 for."

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2 Do you see that?

3 A. I do see that, and I did say that.

4 Q. Does this statement refer to the microbiology study  
5 that was conducted in 2009?

6 A. Yes.

7 Q. What did you mean by "having to make up the  
8 bacterial side of things on the day"?

9 A. What that means is that there was not  
10 a pre-ordained plan for how the microbiology sampling would  
11 work. The plan was formulated on the day of the experiment  
12 when it was apparent what the equipment we had was, how we  
13 would utilize it, and how we might use any results.

14 Q. So there was no advance planning with respect to  
15 the bacterial side of things in this experiment?

16 A. The advance planning came in the form of having  
17 appropriate plates produced and brought to the operating  
18 room, and providing the machine itself, or acquiring the  
19 machine, or getting it to the right area. But in terms of  
20 how plates were positioned, how they were used, and how the  
21 sampling was done, that was decided on the day.

22 Q. Given the issues associated with the location of  
23 the sampler, the failure to use a Casella sampler, the  
24 limitations of the Handilaz particle counter, the duration  
25 of the experiment, you don't stand by the results of this



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2 other study, do you?

3 A. The results are the results. I don't -- the  
4 experiment was performed in a way which seemed appropriate  
5 at the time, but I don't think the results are  
6 representative of real clinical practice. The results were  
7 honestly acquired and obtained, but in my opinion they don't  
8 show anything that is particularly relevant to clinical  
9 practice. So the process of gaining these results was a  
10 good learning experience for me, in terms of producing  
11 further study and research, and that's how I consider this  
12 exercise to be: a good learning experience. But the results  
13 that were outputted from it were not sufficient, in terms of  
14 quantity and quality, to draw any meaningful conclusions.  
15 And that is why -- it is likely to be why it was rejected,  
16 in my opinion, and why I did not pursue it further.

17 Q. You also mentioned yesterday that the patient was  
18 not positioned under standard protocol for a total knee  
19 arthroplasty or total hip arthroplasty; correct?

20 A. That's correct.

21 Q. There were no trays in the OR during this  
22 experiment?

23 A. That's correct.

24 Q. The overhead light position was neither recorded  
25 nor controlled during the experiment?

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2 A. Correct.

3 Q. There was only one person in the in operating room  
4 at the time in which the experiment was conducted, when in  
5 other situations there would be more?

6 A. There was more than one person in the room. There  
7 was not more than one person within the laminar flow  
8 boundary, and there were no more than, I think, four people  
9 in the room at any one time. And they were standing well  
10 away from the laminar flow boundary, which is not standard  
11 practice, and would not be what I would expect in a surgery.

12 Q. To the extent that this data shows that there were  
13 more particles in the room when the surgeon entered than  
14 when the Bair Hugger was on without the surgeon, did you  
15 control for the Bair Hugger being off when the surgeon was  
16 in the room?

17 MR. C. GORDON: Object to the form of the  
18 question.

19 A. Not as far as I can remember.

20 BY MR. SACCHET:

21 Q. So, even if there were increased particle counts  
22 when a surgeon entered the room, there would be no way of  
23 telling whether those increased particle counts were  
24 a product of the Bair Hugger by itself, the Bair Hugger in  
25 combination with the surgeon, or the surgeon by him or

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2 herself?

3 A. There's no way of proving a correlation, or  
4 demonstrating statistically significant correlation between  
5 those conditions.

6 Q. So the increase, if any, in particle counts when  
7 the surgeon entered the room versus when the Bair Hugger was  
8 on by itself, did not have -- no determination of  
9 statistical significance was made?

10 A. No statistical analysis performed, and so no  
11 statistical -- statistically significant conclusions can be  
12 drawn from it.

13 MR. SACCHET: Why don't we take a break?

14 THE VIDEOGRAPHER: Going off the record at three  
15 minutes past twelve.

16 (12:03 p.m.)

17 (Break taken.)

18 (1:06 p.m.)

19 THE VIDEOGRAPHER: Back on the record at six  
20 minutes past one.

21 BY MR. SACCHET:

22 Q. Mr. McGovern, we're going to move now to the  
23 article you co-published, entitled "Forced-air warming and  
24 ultra-clean ventilation do not mix."

25 A. Yes.

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2 (Exhibit 13 marked for identification)

3 Q. You are a co-author of this paper; correct?

4 A. Correct.

5 Q. As are Mr. Albrecht, Mr. Belani, Mr. Nacathsheim,  
6 Mr. Partington, and Mr. or Ms. Carluke?

7 A. Mr. Carluke.

8 Q. Mr. Carluke and Mr. Reed; correct?

9 A. Correct.

10 Q. There were two parts to this study: one  
11 experimental regarding bubble counts, and another regarding  
12 observational data; correct?

13 A. Correct.

14 Q. And with respect to the experimental part, you  
15 analyzed a hip replacement surgery and lumbar spine surgery?

16 A. Simulated versions of those, yes.

17 Q. Were you involved in the design and set-up of those  
18 two simulations?

19 A. Yes.

20 Q. What was your role in designing those two  
21 simulations?

22 A. My role was to work with Mike Reed and Mark  
23 Albrecht to set the operating room up to understand how  
24 helium bubbles were flowing in the room, to suggest set-ups  
25 which were representative of real surgical situations, and

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2 to ensure that the simulation that was undertaken was as  
3 close as practicable to a real-world scenario.

4 Q. Was the operating room in which the simulations  
5 were performed a actual orthopedic operating room?

6 A. It was indeed.

7 Q. And in that operating room, was there laminar flow?

8 A. There was.

9 Q. Based on the text of the study, isn't it true that  
10 the laminar flow exceeded minimum standard requirements for  
11 laminar flow in operating rooms?

12 A. It did. Laminar flow in that hospital trust is  
13 regularly tested and was a -- that the laminar flow unit was  
14 functioning correctly and adequately for orthopedic  
15 operating procedures.

16 Q. The bubble generator that you used was specifically  
17 designed for, and validated for, testing air currents;  
18 correct?

19 A. I understand that it was, yes.

20 Q. And for both procedures -- simulations, rather --  
21 you testified yesterday that they were draped according to  
22 realistic protocols and procedures?

23 A. That is correct.

24 Q. The adhesive edges of the drape were sealed in  
25 accordance with standard protocol?

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2 A. They were attached to the mannequin as they usually  
3 would be to a real patient, yes.

4 Q. And you and Mr. Albrecht even checked to make sure  
5 that there were no air tunnels for air to escape prior to  
6 performing the experiment; correct?

7 A. We made every effort to ensure that the seal was as  
8 effective as it could be, and we made every effort to avoid  
9 the possibility of any air tunnels under the drapes blowing  
10 directly into the operative field, yes.

11 Q. And the simulations were randomized, were they not?

12 A. The simulations were randomized, yes.

13 Q. In terms of the design of the experiment, you  
14 tracked bubble counts using a sequence of five photographs  
15 at 10-second intervals; correct?

16 A. Yes, we used photographs at intervals to track  
17 bubbles in a specific area, yes.

18 Q. And the specific design of the experiment is what  
19 is known as a 2x3 vectorial design?

20 A. Yes.

21 Q. And the factors within the 2x3 vectorial design  
22 were 2 being the Hotdog versus the Bair Hugger?

23 A. Yes.

24 Q. And the 3 being the height of the drape, 1 at no  
25 drape, the other at half drape, and the final at full drape;

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2 correct?

3 A. Correct.

4 Q. If we could turn to Figure 5 on internal page 1540.

5 A. Yes.

6 Q. Figure 5 displays the sum of bubble counts for each  
7 run of the 2x3 vectorial design; correct?

8 A. Yes.

9 Q. And with respect to no drape, otherwise known as  
10 "laid down", conductive fabric warming resulted in zero  
11 bubbles over the surgical site; correct?

12 A. Yes.

13 Q. In contrast to zero bubbles over the surgical site,  
14 the use of a forced-air warming, namely the Bair Hugger,  
15 resulted in three bubbles over the surgical site?

16 A. It shows some bubbles. I don't remember -- it  
17 doesn't show that on this table, as far as I can see.

18 Q. If you look at the second paragraph of the  
19 "Results" section of the study on the same page, do you see,  
20 in the last clause of that paragraph --

21 A. Yes.

22 Q. -- it states: "... and laid-down (0 versus 3 ..."

23 A. It does a lay down 0 versus 3, yes.

24 Q. So there were three bubbles with the use of  
25 a forced-air warming device, namely the use of a Bair Hugger

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2 when the drape is laid down, yes?

3 A. To the best of my knowledge, yes.

4 Q. At half height, there were zero bubbles over the  
5 surgical site with respect to the use of the Hotdog  
6 conductive fabric warming device; correct?

7 A. Yes.

8 Q. And in contrast to zero bubbles at the surgical  
9 site, the forced-air warming device --

10 (Reporter clarification.)

11 MR. SACCHET: Why don't I -- we'll just strike the  
12 question and I'll re-ask it for the purposes of the record.

13 BY MR. SACCHET:

14 Q. At half height, the forced-air warming device,  
15 namely the Bair Hugger, resulted in 68 bubbles over the  
16 surgical site; correct?

17 A. Could you just direct me to that? Ah, no, could  
18 you direct me to that paragraph in the text, please?

19 Q. Sure. So, in the second paragraph of the "Results"  
20 section, the third-to-last clause states:

21 "Drape configurations at half height (0 versus  
22 68 ..."

23 A. Yes, seen. Yes.

24 Q. And finally, at the full drape height, we can just  
25 refer -- instead of Figure 5, which seems to be more



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2 confusing than helpful -- back to the text. There were zero  
3 bubbles with respect to conductive fabric warming and one  
4 bubble with respect to forced-air warming, in the last  
5 sentence of that paragraph; do you see that?

6 A. Yes.

7 Q. So, all told, with respect to the drape laid down,  
8 the drape at half height, and the drape at full height,  
9 there were no bubbles produced by the conductive fabric  
10 warming device during any of the runs; correct?

11 A. That is what these results indicate.

12 Q. And with respect to the drapes at half height, and  
13 laid down, the differences in bubble counts between the  
14 Hotdog and the Bair Hugger were statistically significant?

15 A. That is what these results and the statistical  
16 analysis indicates.

17 Q. This study was submitted to the Journal of Bone and  
18 Joint Surgery; correct?

19 A. The British volume of that journal, yes.

20 Q. And some of the reviewers, or all of the reviewers,  
21 have expertise in the field of bone and joint surgery;  
22 correct?

23 A. Yes. The reviewers will have been selected for  
24 their specific expertise and their ability to peer review  
25 papers in this field for this journal.

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2 Q. And the paper was accepted for publication after  
3 the peer-review process in this journal; correct?

4 A. Correct.

5 Q. Do you recall one of the reviewers stating that the  
6 study was conducted in a clear, methodical and productive  
7 fashion?

8 A. Yes.

9 Q. So the editors of this journal ultimately accepted,  
10 as stated in this study, that the Bair Hugger produced more  
11 bubbles over the surgical site than a conductive fabric  
12 warming device?

13 A. The experiment in which the Bair Hugger was  
14 compared with the conductive fabric forming device resulted  
15 in more bubbles in the vicinity of the operative field for  
16 the Bair Hugger condition than for the conductive fabric  
17 warming condition.

18 Q. Albeit not in this study, but a different study, do  
19 you recall stating that smaller airborne particles, such as  
20 free-floating bacteria and skin cell fragments, had similar  
21 airborne characteristics as neutrally buoyant detergent  
22 bubbles?

23 A. I may have stated that, but I would need to be  
24 directed to the document to refresh my memory.

25 (Exhibit 14 marked for identification)

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2 Q. If you could please turn to internal page 409, the  
3 last paragraph. The last full paragraph, I should say, in  
4 the right-hand column. The sentence states:

5 "These concerns are most relevant for smaller  
6 airborne particles, less than or equal to 10 microns,  
7 such as free-floating bacteria and skin cell fragments,  
8 having similar airborne characteristics to the  
9 neutrally buoyant detergent bubbles studied ..."

10 Do you see that?

11 A. I do see that.

12 Q. This paper was authored by you and others; correct?

13 A. Correct.

14 Q. Do you stand by that statement?

15 A. That statement is reasonable me. It does not have  
16 a reference for the relationship between free-floating  
17 bacteria, skin cell fragments and helium bubbles having  
18 similar airborne characteristics. I believe that to be the  
19 case, but it would be preferable, in my opinion, for that  
20 statement to be referenced to a peer-reviewed paper. And  
21 although I believe that to be the case, I could not say that  
22 that is fact without further evidence.

23 Q. This paper, namely Patient Warming Excess Heat by  
24 you and Mr. Belani and others, was peer-reviewed; correct?

25 A. It was peer-reviewed, yes.

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2 Q. It was published in Anesthesia & Analgesia;  
3 correct?

4 A. Analgesia, yes.

5 Q. So had this statement been of great concern to the  
6 editors, they would have asked for a revision of that  
7 statement; correct?

8 A. I think that would probably -- (overspeaking) --  
9 (Reporter clarification.)

10 MR. C. GORDON: The objection again? Both form  
11 and lack of foundation.

12 A. Could you just repeat the question, please?

13 BY MR. SACCHET:

14 Q. Sure. Had there been a great issue with this  
15 particular statement, the editors may have required you to  
16 alter it in some way; correct?

17 A. The action of the editors would be their decision,  
18 but I would expect that a statement which, were I reviewing  
19 a paper, if I had identified a statement which I felt to be  
20 questionable, I would have challenged it and expected it to  
21 be justified or removed.

22 Q. And in other papers you have co-authored and  
23 participated in the peer-review process, editors have asked  
24 for revisions of particular sentences?

25 A. Yes, that's absolutely true.

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2 Q. And this particular sentence was published in final  
3 form, as it says in this paper?

4 A. This sentence, as part of this paper, was  
5 peer-reviewed and approved for publication.

6 Q. Do you have any reason to doubt the bubble count  
7 results of the McGovern paper?

8 A. I do not.

9 Q. You did not receive any compensation from Augustine  
10 Biomedical & Design, or any of its predecessor entities,  
11 with respect to conducting this study?

12 A. No.

13 Q. In fact, it cost you a sum of money to conduct this  
14 study?

15 A. Overall, this study -- the conducting of this study  
16 involved me working at weekends in my own hours, traveling  
17 to and from the hospital on my own time, and at my own  
18 expense. There were -- some equipment was purchased, and at  
19 the time, I received expenses for that equipment to be  
20 purchased, I did -- but I received that from the healthcare  
21 trust that I worked for. I did not receive any money  
22 directly from Augustine at this time for this paper, to my  
23 knowledge.

24 Q. The fact that Mr. Albrecht may have been employed  
25 by Augustine Biomedical & Design, or any of its predecessor

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2 entities at this time, had no influence on your  
3 participation in this study?

4 A. It had no influence on my participation in this  
5 study.

6 Q. Let's now move to the observational aspect of the  
7 study. Were you involved in the collection of any of the  
8 data with respect to the observational information present  
9 in this study?

10 A. I was not.

11 Q. Were you aware that other co-authors of this study,  
12 such as Mr. Reed, made great efforts to collect as much data  
13 as possible before publishing the paper?

14 A. Yes.

15 MR. C. GORDON: Object to the form of the  
16 question.

17 BY MR. SACCHET:

18 Q. For example, in prior manuscripts of this study,  
19 one of which you looked at yesterday, the period of time in  
20 which infection rates were analyzed was from September 2008  
21 to September 2010, a two-year period; correct?

22 A. Yes.

23 Q. Whereas the published paper, as shown in figure 7  
24 of the study, the date range was July 2008 to January 2011;  
25 correct?

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2 A. Correct.

3 Q. That period is longer than the original period in  
4 one of the initial manuscripts of this paper; correct?

5 A. Indeed it is.

6 Q. In the prior manuscript of this study, the  
7 infection data for conductive fabric warming devices showed  
8 zero infections; correct?

9 A. In the previous draft that you've mentioned, that's  
10 correct.

11 Q. Whereas in this study, there were three infections  
12 that occurred when a conductive fabric warming device was  
13 used; correct?

14 A. That is correct.

15 Q. So there was no intent or effort on the part of the  
16 co-authors to artificially limit the dataset or time period  
17 in which this data was analyzed, in order to skew the  
18 results?

19 A. That is correct. As much data as was available was  
20 included in the paper. When the process of writing and  
21 reviewing the paper went beyond the earlier limit that you  
22 discussed, and more data was available, it was included, so  
23 that as much data as possible could be included, to my  
24 memory.

25 Q. And yesterday you were asked about being concerned

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2 with the data that was prevented in the initial draft of the  
3 paper; correct?

4 A. Yes.

5 Q. And do you recall, upon reviewing updated data,  
6 being pleased with the dataset?

7 MR. C. GORDON: Object to the form of the  
8 question.

9 A. I don't recall being pleased or displeased with the  
10 dataset.

11 BY MR. SACCHET:

12 (Exhibit 15 marked for identification)

13 Q. This is an e-mail dated -- or e-mails dated  
14 February 1, 2011; correct?

15 A. Yes.

16 Q. In the first e-mail, Mr. Albrecht writes to  
17 Mr. Reed, yourself and others; correct?

18 A. Yes.

19 Q. And he says:

20 "Guys,

21 "Here it is, including the updated joint  
22 infection data covering about 6-9 months of conductive  
23 fabric warming usage."

24 Do you see that?

25 A. I do.



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2 Q. And below that, you respond directly to  
3 Mr. Albrecht; correct?

4 A. That is correct.

5 Q. And you say:

6 "Looks fantastic, particularly with the new  
7 data... thanks!"

8 A. Correct.

9 Q. So, based on the updated data, had you been  
10 concerned prior to that time, at this point you were pleased  
11 with the data?

12 MR. C. GORDON: Object to the form of the  
13 question.

14 A. I don't believe that indicates that I was concerned  
15 with the data. That statement represents a sense of my  
16 being pleased that the paper had been finished and  
17 completed, it was ready for submission, and that I was  
18 satisfied with the quality of the paper and I felt that it  
19 was a good piece of work.

20 BY MR. SACCHET:

21 Q. And you were satisfied with the new data?

22 A. I was satisfied with the new data.

23 Q. Let's actually look at some of the specifics about  
24 the observational data that was collected.

25 A. Okay.

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2 Q. I don't necessarily expect you to remember all this  
3 from memory, so I'm happy to direct you to particular pages.  
4 But do you recall that the final dataset had 1,437 patients?

5 A. That sounds about in the right ballpark, but I  
6 don't remember the exact number.

7 Q. If you look at page 1541 internally of the study.  
8 Sorry, going back to exhibit 13.

9 A. Yes.

10 Q. The column on the left bears a bold section header  
11 entitled "Joint infection risks", and it states:

12 "The demographics of 1437 patients undergoing  
13 hip and knee replacements revealed no significant  
14 difference between the two types of warming for SSI  
15 risk factors of age, type of surgery, diabetes and  
16 length of pre-operative stay."

17 Correct?

18 A. Yes, correct.

19 Q. So the final dataset involved 1,437 patients;  
20 correct?

21 A. Yes.

22 Q. If I can draw your attention to table II, which is  
23 on the next page. And if you look at, I guess, the bottom  
24 third of that table, there are lines entitled "Patient  
25 warming device."

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2 And beneath that: "Conductive [warming] fabric  
3 [subset] knee [subset] hip."

4 And then: "Forced air [subset] knee [subset] hip";  
5 correct?

6 A. Yes.

7 Q. And then the first column of data relates to  
8 developing an infection; correct?

9 A. Yes.

10 Q. And the second set relates to not developing an  
11 infection?

12 A. Yes.

13 Q. Correct. So, in order to determine how many  
14 patients were in each group, whether it be conductive fabric  
15 or forced-air warming, one would need to add those  
16 developing an infection with those not developing an  
17 infection; correct?

18 A. Could you repeat that, please?

19 Q. In order to determine the total population of those  
20 who received conductive fabric warming, one would need to  
21 add the three patients who developed an infection with the  
22 368 who did not develop an infection; correct?

23 A. Yes.

24 Q. So the total population of those receiving  
25 conductive fabric warming was 371 patients; correct?

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2 A. Yes.

3 Q. And with respect to forced-air warming, the total  
4 population was 1,066; correct?

5 A. 1,034 plus 32, yes.

6 Q. On the same table, 3 out of the 371 patients who  
7 received conductive fabric forming developed an infection;  
8 correct?

9 A. Yes.

10 Q. And those infections are specific to deep joint  
11 infections; correct?

12 A. That information is not in this table. You'd have  
13 to direct me to where it specifically says that in the paper  
14 for me to be able to confirm that.

15 Q. So the subsets of each warmer are knee and hip, and  
16 knee and hip; correct?

17 A. Correct.

18 Q. So those would be joint infections; correct?

19 A. They ... they indicate an infection in a knee  
20 operation and a hip operation. But your comment as to  
21 whether it was a deep joint infection, I don't know if that  
22 has been specified in the text. I don't remember.

23 Q. If you could look at the first page of the study,  
24 in the third paragraph in bold, it states:

25 "A significant increase in deep joint

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2 infection, as demonstrated by an elevated infection  
3 odds ratio [of 3.8 with a p value 0.24] was  
4 identified."

5 Do you see that?

6 A. Yes, and I agree, then, that these refer to deep  
7 joint infection.

8 Q. So 3 out of the 371 patients receiving conductive  
9 fabric warming developed a deep joint infection; correct?

10 A. That is what this data appears to show.

11 Q. And 32 out of the 1,066 patients receiving  
12 forced-air warming developed an infection; correct?

13 A. That is how I interpret this data.

14 Q. And the corresponding percentages, with respect to  
15 infections for each warming group, was 0.8 percent  
16 infections for conductive fabric warming versus 3.0  
17 infections for forced-air warming; correct?

18 A. That is what this data shows.

19 Q. Because the data was specific to deep joint  
20 infections, the data did not analyze wound infections more  
21 generally?

22 A. That is correct, to the best of my knowledge.

23 Q. So, things like superficial infections and hematoma  
24 were not analyzed by these particular figures?

25 A. That is what I understand from this, yes.

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2 (Exhibit 16 marked for identification)

3 Q. So it is a bit of in unwieldy document but we'll do  
4 our best. As you can see, it is an Excel spreadsheet?

5 A. Yes.

6 Q. That was included in your production of documents;  
7 correct?

8 A. Yes.

9 Q. The cells have various labels, the first being in  
10 column AWG; do you see that?

11 A. I do.

12 Q. Does "WG" likely stand for Wansbeck Hospital?

13 A. Yes.

14 Q. Column B has numbers ranging from, I believe, 39 to  
15 87. I suspect that they are patient ages; is that correct?

16 A. That seems likely, yes.

17 Q. Column C has various letters with numbers, all with  
18 the first letter W. Is that some type of patient code?

19 A. It may be, because some of them are the same. Ah,  
20 it appears, actually, that they correspond to the operation  
21 code.

22 Q. Okay.

23 A. So 371 appears to correspond to hip, and I suspect  
24 that --

25 Q. Oh, yes. There are only two types: 401 versus 371.

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2 A. So I suspect that is what that means.

3 Q. Okay. And in column D, in fact, the type of  
4 arthroplasty is labeled as either hip or knee; correct?

5 A. Yes.

6 Q. And in column E, the date in which the surgery  
7 occurred?

8 A. Most likely, yes.

9 Q. Okay. Now if we flip the page, in column --  
10 actually, flipping to the final page.

11 A. Yes.

12 Q. Column BA indicates whether it was an intestinal or  
13 skin carried pathogen?

14 A. BA? No.

15 Q. What are the markings "Intestinal" versus "Skin  
16 Carried"?

17 A. I'm on sheet 2, page 2. Are we on sheet 1?

18 Q. Let's look at sheet 3 -- I mean sheet 1, page 3.

19 A. Right, okay. So that's column BA, yes.

20 Q. And the "B" specifies the type of bacteria?

21 A. Yes.

22 Q. And "BC" is the type of warming device?

23 A. Yes. I don't understand why -- okay, yeah, it  
24 does. It states the type of warming device, yes.

25 Q. Okay. Are you familiar with the fact that the

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2 study period of the McGovern study started on July 2008?

3 A. I would have to check the paper to confirm that.

4 Q. If you go back to tab 44 and look at the -- I'm  
5 sorry, if you can go back to your exhibit 13.

6 A. Yes.

7 Q. There is the infection graph?

8 A. Yes, July 2008.

9 Q. Okay. And the first five procedures that were  
10 performed, as designated in column E on page 1 of sheet 1,  
11 all precede July 2008; correct?

12 A. Yes.

13 Q. So those particular infections were not included in  
14 the published McGovern study; correct? Because --

15 A. Because?

16 Q. Because it preceded the time in which the McGovern  
17 study analyzed the data; correct?

18 A. It looks that way, yes.

19 Q. Okay. However, the sixth entry started on July 1,  
20 2008, which is within the period of the study; correct?

21 A. That appears to be so. It could be that the date  
22 started just after the first -- but no, it is July, because  
23 the next one is August, so yes.

24 Q. Okay. And as you can see on sheet 1, page 3, in  
25 column BC, there are six cells entitled "Transition"; do you



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2 see that?

3 A. Yes.

4 Q. There was also a transition period in the McGovern  
5 study, was there not?

6 A. Yes.

7 Q. And those particular infections that occurred in  
8 the transition period were not part of the conductive fabric  
9 warming period or the forced-air warming period; correct?

10 A. Yes, I believe so.

11 Q. So, now that we have established that, if we  
12 exclude the first five cells which occurred prior to 1 July  
13 2008, and we exclude the six cells bearing the label  
14 "Transition", how many cells do you count in between, which  
15 would be cells 6 through 35?

16 A. 29. Huh? Yeah.

17 Q. You might want to count them out, just to be sure.  
18 So 6 through 35.

19 A. Inclusive?

20 Q. Yes.?

21 A. Well, inclusive, 26.

22 Q. So we've got 6, 7, 8, 9, 10. That's 5, right?

23 A. Yes.

24 Q. 11, 12, 13, 14, 15, another 5 to make 10?

25 A. Yes.

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2 Q. 16, 17, 18, 19, 20, another 5 to make 15?

3 A. Yes.

4 Q. 21, 22, 23, 24, 25, another 5 to make 20?

5 A. Yes.

6 Q. 26, 27, 28, 29, 30, another 5 to make 25?

7 A. Yes.

8 Q. And 31, 32, 33, 34, 35, to make 30?

9 A. Yes.

10 Q. And then 36 is February 23, 2010, which  
11 I improperly excluded, but it is not part of the transition  
12 cell, correct? Cell 36, with BC?

13 A. 37 is transition, so 36 is part of that.

14 Q. So it would be 31 --

15 A. Right, okay.

16 Q. -- FAW infections; correct?

17 A. Okay.

18 Q. And now if we look at cell 44 in column BC, what is  
19 the marking of that device?

20 A. FAW.

21 Q. In total, how many forced-air warming device  
22 related infections were there? 31 plus 1?

23 A. 32.

24 Q. 32 infections for forced-air warming; correct?

25 A. Yes.

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2 MR. C. GORDON: What was the last number you had?

3 MR. SACCHET: Yes, cell number 44.

4 MR. C. GORDON: 44?

5 MR. SACCHET: Yes.

6 THE WITNESS: Row number.

7 MR. SACCHET: Oh, I apologize. 44C, labeled  
8 "FAW".

9 MR. C. GORDON: From September 15?

10 BY MR. SACCHET:

11 Q. Labeled "FAW". If we could now look at the cells  
12 43, 45 and 46, what is their label in the BC column?

13 A. "CFW".

14 Q. How many total CFW infections is that?

15 A. 3.

16 Q. So there are 32 forced-air warming infections and 3  
17 conductive fabric warming infections; correct?

18 A. Yes.

19 Q. If we turn back to the McGovern study, exhibit 13,  
20 and look back to table 2.

21 A. Yes.

22 Q. Are there three conductive fabric warming related  
23 infections?

24 A. Indeed there are.

25 Q. Are there 32 forced-air warming related infections?

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2 A. Yes.

3 Q. Does the data presented in this Excel spreadsheet  
4 match the data presented in the published study?

5 A. The data we've discussed matches the data in the  
6 published study.

7 Q. Now let's look at the significance of the data.  
8 Table 2 shows a P value of 0.024 with respect to patient  
9 warming device; correct?

10 A. Yes.

11 Q. A P value of 0.024 is statistically significant, is  
12 it not?

13 A. Yes.

14 Q. That would indicate that there was a sufficiently  
15 powered difference between infection rates in patients who  
16 received conductive fabric warming devices versus those who  
17 received forced-air warming devices; correct?

18 A. That is what this analysis would suggest, yes.

19 Q. Table 2 also bears the number 3.8 under "Odds  
20 ratio"; do you see that?

21 A. Yes, yes.

22 Q. What does that number signify?

23 A. I am not happy to define that at the moment,  
24 because I may make a mistake.

25 Q. Does it relate to, on the first page of the study,

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2 in the line that I previously read, which is in bold in the  
3 third paragraph, where it states "A significant increase in  
4 deep joint infections as demonstrated by an elevated  
5 infection odds ratio of 3.8 was identified during a period  
6 when forced-air warming was used compared to a period when  
7 conductive fabric warming was used"?

8 A. That is what this refers to.

9 Q. So there was a 3.8 times more likely rate that  
10 a patient would incur a deep joint infection with the use of  
11 a forced-air warming device than with a conductive fabric  
12 warming device; correct?

13 A. That is what I understand from these data and from  
14 this analysis.

15 Q. Do you recall Mr. Reed informing you that "The data  
16 was dramatic and will demonstrate to reviewers that there  
17 was a genuine change with conductive fabric warming rather  
18 than a steady decline due to other reasons"?

19 A. I don't recall him saying that.

20 (Exhibit 17 marked for identification)

21 Q. If I could direct your attention to page 2 of 3.  
22 There is an e-mail dated February 19, 2011, from Mike Reed  
23 to Mr. Albrecht and yourself and Mr. Belani and  
24 Mr. Nacthsheim; correct?

25 A. Yes.

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2 Q. The final two lines of the large paragraph in the  
3 middle of the page states:

4 "It is quite dramatic and will demonstrate to  
5 reviewers that there was a genuine change with CFW  
6 rather than a steady decline due to other reasons."

7 Do you see that?

8 A. That is what it says here, yes.

9 Q. Does that refresh your recollection that Mr. Reed  
10 stated that the data showed a genuine change with conductive  
11 fabric warming, rather than a steady decline due to other  
12 reasons?

13 A. It does refresh my memory to that effect.

14 Q. Do you have any reason to doubt Mr. Reed's ability  
15 to make such a statement?

16 A. I do not.

17 Q. You have all the confidence that you could that  
18 Mr. Reed would accurately state such a statement?

19 A. Yes.

20 Q. Do you recall the reviewers from the Journal of  
21 Bone and Joint Surgery stating that there were -- that the  
22 data in your study supported serious issues with forced-air  
23 warming devices?

24 A. I don't recall their comments to that effect.

25 (Exhibit 18 marked for identification)

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2 A. Thank you.

3 Q. This is a initial e-mail from Mr. Albrecht to  
4 yourself on May 19, 2011; correct?

5 A. Yes.

6 Q. He says, "See reviewer's comments below (only  
7 minor)."

8 A. Yes.

9 Q. Below that is an e-mail from -- actually a letter  
10 from James Scott, an editor of the journal?

11 A. Yes.

12 Q. To Mr. Albrecht?

13 A. Yes.

14 Q. It says:

15 "Thank you for submitting your paper for  
16 consideration by the Journal of Bone and Joint Surgery.  
17 It has been reviewed by experts in the field and by  
18 members of the editorial staff";

19 Does it not?

20 A. It does.

21 Q. On the third page of this e-mail there are comments  
22 from reviewer 2, correct? Which is designated on the second  
23 page but carrying over on to the third page?

24 A. Correct.

25 Q. In the first full paragraph, the reviewer states:

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2 "The second part of the paper is a study of  
3 the infection in the cases done in their unit over  
4 a period of years before, during and after the  
5 transition from the forced-air warming apparatus to the  
6 conductive material heating apparatus."

7 Do you see that?

8 A. I do.

9 Q. The reviewer goes on to state:

10 "This demonstrates that there were actual  
11 changes in infection rates which would fit well with  
12 the experimental data and therefore support the  
13 contention that there is a serious issue to be  
14 addressed with some of the warming devices."

15 Do you see that?

16 A. I do.

17 Q. Does that refresh your recollection that one of the  
18 editors of the Journal of Bone and Joint Surgery said that  
19 the study supported serious issues with respect to warming  
20 devices?

21 A. One of the peer reviewers said that.

22 Q. One of the peer reviewers?

23 A. Yes.

24 Q. Yesterday you were asked about some of the  
25 potential limitations of the study; correct?



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2 A. Yes.

3 Q. You were asked about particular patient  
4 demographics?

5 A. Yes.

6 Q. And table 1 of the study itself shows that some  
7 patient-specific demographics were similar between the  
8 patient groups who received forced-air warming versus  
9 conductive fabric warming; correct?

10 A. Yes.

11 Q. And table 2 shows that, as to those particular  
12 patient-specific demographics, including age, diabetes and  
13 length of pre-operative stay, that they did not  
14 significantly impact infection rates; correct?

15 A. That is what I understand from this data.

16 Q. With regard to other potential patient-specific  
17 demographics, including things like obesity, or  
18 incontinence, or fitness for surgery, do you have any reason  
19 to doubt that the two patient groups between forced-air  
20 warming and conductive fabric warming were different?

21 A. No.

22 Q. This data was observational in nature; right?

23 A. Correct.

24 Q. Observational data is a legitimate scientific  
25 methodology; correct?

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2 MR. C. GORDON: Object to the form of the  
3 question.

4 A. It is -- well, data is not a methodology.  
5 BY MR. SACCHET:

6 Q. Studies.

7 A. But observational studies are legitimate scientific  
8 studies, in my opinion.

9 Q. In the absence of a randomized controlled study,  
10 observational studies are considered to be the next best  
11 alternative; correct?

12 A. I wouldn't know if they were the next best  
13 alternative, but they are a valuable component of the total  
14 body of knowledge on a subject.

15 Q. Are you aware that in other healthcare  
16 circumstances, such as the use of tobacco and cancer rates,  
17 that for a very long period of time there was never  
18 a randomized controlled trial that proved causation between  
19 the use of tobacco and cancer?

20 A. Absolutely, yes.

21 Q. And all that there was to rely on for many, many  
22 years, were observational studies?

23 A. Absolutely, yes.

24 Q. And we all know, beyond peradventure, that tobacco  
25 causes cancer?

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2 A. Yes.

3 Q. In order to conduct a randomized controlled trial  
4 with respect to infection rates in orthopedic procedures,  
5 you'd need a huge amount of funding, wouldn't you?

6 A. Yes.

7 Q. The patient population would have to be massive for  
8 it to be sufficiently powered?

9 A. Yes.

10 Q. Those two factors would make it difficult for a lot  
11 of scientists to conduct a randomized controlled trial on  
12 the rates of infection in joints between the use of  
13 a forced-air warming device and a conductive fabric warming  
14 device; correct?

15 A. Yes, amongst others.

16 Q. In fact, there is no study to this day that's  
17 a randomized controlled trial. I'll strike that.

18 So, despite the fact that a randomized  
19 controlled trial has not been conducted, this  
20 observational data is valuable?

21 A. Yes, I believe this observational data is valuable.

22 Q. You were also asked yesterday about the change in  
23 antibiotic protocol, were you not?

24 A. Yes.

25 Q. And we now know, through our conversation, that the

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2 period of data that was collected for this study began on  
3 July 1, 2008; correct?

4 A. Yes.

5 Q. And there was a transition in the middle between  
6 forced-air warming to conductive fabric warming; correct?

7 A. Yes.

8 Q. Okay. If we can turn to page 1540 of exhibit 13,  
9 there is a column on the left-hand side entitled "Joint  
10 infection data"; do you see that?

11 A. I do.

12 Q. Do you see where it states, kind of in the middle  
13 of that large paragraph:

14 "From July 2008 to February 2009, a single dose of  
15 gentamicin 4.5 mg/kg was advantage given at induction."

16 A. I do.

17 Q. "In March 2009 this was changed to teicoplanin  
18 400 mg and gentamicin 3 mg/kg."

19 Do you see that?

20 A. Yes.

21 Q. So, in other words, gentamicin was applied during  
22 the forced-air warming period from July 1 to the end of  
23 February 2009, and then there was a combination of  
24 gentamicin and teicoplanin administered thereafter; correct?

25 A. For -- yes, there was, yeah.

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2 Q. For the purposes of our conversation, let's refer  
3 to the administration of only gentamicin as protocol 1;  
4 okay?

5 A. Okay.

6 Q. And let's refer to the combination of gentamicin  
7 and teicoplanin as protocol 2, okay?

8 A. Okay.

9 Q. Assuming the change in protocols did not affect  
10 deep joint infection rates between the warming devices,  
11 would you consider the change in antibiotic to be  
12 a confounding variable?

13 MR. C. GORDON: Object to the form of the  
14 question: incomplete hypothetical, assumes facts not in  
15 evidence.

16 A. I can't comment on that. I can't predict what the  
17 outcome would be, given an assumption which hasn't been  
18 tested.

19 BY MR. SACCHET:

20 Q. But if there was no difference in infection rates  
21 between the use of protocol 1 and 2, how could it be  
22 a confounding variable?

23 A. If there was no difference in infections caused by  
24 protocol -- infections in the situation of protocol 1 and  
25 protocol 2, then there was no difference in the infections

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2 between protocol 1 and protocol 2. But that's --

3 Q. A change in antibiotic protocol would not be  
4 a confounding factor with respect to infection rates?

5 (Reporter clarification.)

6 A. If the change in antibiotic protocol made no  
7 difference to infections, then the change in antibiotic  
8 protocol would make no difference to infection rates.

9 Q. And let's say, with respect to protocol 2, that  
10 there is actually an increase in infections between those  
11 who received the same warming therapy versus those who  
12 received protocol 1.

13 A. Right.

14 Q. Would the change to protocol 2 be the reason for  
15 increased infections?

16 MR. C. GORDON: Same objections.

17 A. I don't know. The hypothetical, 'what would happen  
18 if this antibiotic had an affect' question, is not something  
19 that I can unpick and predict in terms of what did happen or  
20 what would happen. I don't feel able to comment on what  
21 would happen if a -- if part of this data were different or  
22 were removed from this, because the -- a confounding  
23 variable is so complex, and the influence that a confounding  
24 variable has is so complex, that I don't think it is  
25 possible for me to predict what would happen if

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2 a potentially confounding variable were altered.

3 BY MR. SACCHET:

4 Q. Let's look at a document that might help you.

5 (Exhibit 19 marked for identification)

6 A. Thank you.

7 Q. Could you turn to the very last page of this  
8 document. Do you see a table with four rows?

9 A. Yes.

10 Q. Have you seen this table before?

11 A. Not to my recollection.

12 Q. Do you recall being on a string of e-mails in which  
13 you received an attachment called "McGovern data redone"?

14 A. Yes.

15 Q. That's on the third page of this e-mail thread?

16 A. Yes.

17 Q. Does the final page of this set of documents look  
18 like it involves data?

19 A. It looks like it contains numbers which could be  
20 data.

21 Q. And the first row is entitled "Ab Protocol 1/Forced  
22 Air"?

23 A. Yes.

24 Q. Could that mean antibiotic protocol 1 forced air?

25 A. I can't speculate on what this might mean.

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2 Q. Okay. Assuming that it means antibiotic protocol 1  
3 forced-air warming, what is the percent of infections  
4 labeled therein?

5 MR. C. GORDON: Object to the form of the  
6 question: lack of foundation, assumes facts not in evidence.

7 A. The number on that row under "No.(%) Developing  
8 Infection" is 11.

9 BY MR. SACCHET:

10 Q. And the parenthetical next to it is numbered what?

11 A. 2.8.

12 Q. And above that, in the dark blue column, there is a  
13 parenthesis bearing a percent mark; correct?

14 A. Yes.

15 Q. And the title of that column is "Number developing  
16 an infection"; correct?

17 A. Yes.

18 Q. So the parenthetical notation of "2.8" means 2.8  
19 percent developing an infection; correct?

20 MR. C. GORDON: Same objection.

21 A. That is what this number appears to show, from my  
22 reading of this table.

23 Q. And the next line is "Ab Protocol 2/Forced Air"; do  
24 you see that?

25 A. I do see that.



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2 Q. Assuming that means antibiotic protocol 2 forced  
3 air, what is the number of those developing an infection?

4 MR. C. GORDON: Same objection.

5 A. The number written in the table in front of me is  
6 21.

7 BY MR. SACCHET:

8 Q. And what is the percent of those individuals  
9 developing an infection?

10 A. The number in parenthesis next to "21" is "3.1".

11 Q. What is the P value on the far right-hand side with  
12 respect to this row of data?

13 A. The number on the right-hand side of the first row  
14 of this table labeled "P value" is 0.839.

15 Q. That figure is not a statistically significant  
16 P value; correct?

17 A. It's, at the moment, just number in a table which  
18 I have not seen before and can't interpret. So I can't say  
19 anything is statistically significant or not, because I  
20 don't know to what the data refers, and I'm not familiar  
21 with the data. So I cannot say whether this is  
22 statistically significant or not because the data, to me,  
23 doesn't mean anything at the moment.

24 Q. Okay, fair enough. Assuming that there were --  
25 assuming that the change in antibiotic was not a confounding

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2 variable ...

3 A. Right.

4 Q. ... would there be any reason to deselect patients  
5 from the population presented in this study for those who  
6 received a different type of antibiotic than others?

7 A. No, I --

8 MR. C. GORDON: Object to the form of question:  
9 lack of foundation, assumes facts not in evidence,  
10 incomplete hypothetical.

11 A. No, I think that it is not necessary in this case  
12 to exclude patients receiving different antibiotic  
13 prophylaxis regimens from the study, because that change has  
14 been declared in the study. It is for the peer reviewer  
15 and, ultimately, the reader, to decide if that confounding  
16 factor significantly affects the data and how to interpret  
17 that data. But the point in this instance, in my opinion,  
18 is that this is an observational study, and what was  
19 observed was declared and presented clearly. And so, in  
20 that case, to the best efforts of the authors of this paper,  
21 what has happened has been reported, and the results that  
22 have been noted have been reported. And so, that being the  
23 case, I think it is appropriate that the data which was  
24 presented was presented in the way that it was.

25 BY MR. SACCHET:

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2 Q. With respect to bacteria that formed biofilm, does  
3 the biofilm protect the bacteria from antibiotics?

4 A. To my understanding, yes.

5 MR. SACCHET: Why don't we switch the DVD?

6 THE VIDEOGRAPHER: This is the end of DVD 2 in  
7 volume 2 of the deposition of Dr. Paul McGovern. Going off  
8 the record at three minutes past two.

9 (2:03 p.m.)

10 (Break taken.)

11 THE VIDEOGRAPHER: This is the beginning of DVD 3  
12 in volume 2 of the deposition of Dr. Paul McGovern. We're  
13 back on the record at twenty past two.

14 BY MR. SACCHET:

15 Q. Mr. McGovern, in your view, what is a confounding  
16 variable?

17 A. A confounding variable is, in my view, a condition  
18 or a factor, or something which could affect the results of  
19 an experiment or alter them in a way that may or may not be  
20 predictable.

21 Q. You're not aware of any information that protocol 1  
22 (gentamicin) versus protocol 2 (gentamicin plus teicoplanin)  
23 introduced contamination into patients, did it?

24 A. Um --

25 MR. C. GORDON: Object to the form of the

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2 question.

3 A. Altering antibiotics, as you mentioned, between  
4 protocol 1 and protocol 2, would not, in my opinion,  
5 introduce infection into patients in any way.

6 BY MR. SACCHET:

7 Q. If you could look back at the last exhibit that we  
8 marked, which I believe is 19, and turn to page 6 of 8, at  
9 the bottom of this chain is an e-mail from Mr. Reed to  
10 yourself on April 4, 2016; correct?

11 A. Yes.

12 Q. He says:

13 "I'm reviewing periop hypothermia for nice so  
14 we don't want to embark on any related research at the  
15 mo. Likely that will come out in depositions anyway.  
16 We did analyze this before and I presented it at the  
17 Mayo (I think) as one of their anaesthetists raised it  
18 ahead of a PPT I did there. It looked like antibiotics  
19 had no effect."

20 Do you know what that refers to?

21 A. I can speculate, but I don't know with certainty  
22 what this is referring to.

23 Q. So you can see, on page 3 of 8, that there are two  
24 attachments, one entitled "McGovern paper" and the other  
25 entitled "McGovern data redone"; yes?

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2 A. Yes, correct.

3 Q. And on page 2 of 8 there is an e-mail from Scott  
4 Augustine to you?

5 A. Yes.

6 Q. Asking if, or stating:

7 "As you are probably aware, the most common  
8 critique of your paper is the switch in antibiotic  
9 protocols during the FAW period."

10 A. Yes.

11 Q. And then he goes on to, you know, ask whether you  
12 are interested in doing further work on the McGovern paper;  
13 correct?

14 A. Yes.

15 Q. So this statement from Mike Reed, or Mr. Reed,  
16 follows up on that thread, and makes the statement we just  
17 discussed; correct?

18 A. Correct.

19 Q. Is it your understanding that Mr. Reed's statement  
20 related to the McGovern study?

21 A. It's my understanding that Mr. Reed's statement is  
22 likely to refer to antibiotics not having an influence on  
23 infection rate -- or changes in antibiotics not having an  
24 influence on infection rate in the McGovern study.

25 Q. Do you have any reason to doubt Mr. Reed's

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2 expertise in the making of such a statement?

3 A. I do not have any reason to doubt Mr. Reed's  
4 expertise in making such a statement.

5 Q. If we could go back to the study itself, which is  
6 tab -- excuse me, exhibit number 13.

7 A. Yes.

8 Q. And if we turn back to page 1540 internally.

9 A. Yes.

10 Q. We see again the section on the left-hand column  
11 entitled "Joint infection data"; correct?

12 A. Yes.

13 Q. Just down from the prior sentences we reviewed, it  
14 states:

15 "Similarly the thromboprophylaxis regimen  
16 from July 2008 to the end of July 2009 was tinzaparin."

17 Do you see that?

18 A. Tinzaparin, yes.

19 Q. I promise I will keep saying "tinzaparin" but  
20 I apologize for doing so.

21 A. No problem.

22 Q. It then goes on to say:

23 "From August 2009 to February 2010  
24 rivaroxaban was provided from day one post-operatively,  
25 but in February 2010 to the end of the study, this

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2 reverted to tinzaparin from day one post-operatively."

3 A. Yes.

4 Q. Do you see that?

5 A. Yes.

6 Q. Tinzaparin is a low-weight-molecular heparin;  
7 correct?

8 A. Low-molecular-weight heparin, yes.

9 Q. Apologies. Low-molecular-weight heparin. Have you  
10 ever heard of rivaroxaban being referred to as Xarelto?

11 A. Yes.

12 Q. And you're comfortable with the fact that the two  
13 are one and the same?

14 A. Yes.

15 Q. Are you aware that the NHS changed from Xarelto  
16 back to tinzaparin because of wound bleeding, as opposed to  
17 increase infections?

18 MR. C. GORDON: Objection to the form of the  
19 question. Lacks foundation, assumes facts not in reference.

20 A. You say NHS?

21 BY MR. SACCHET:

22 Q. NHS.

23 A. Are you referring to NHS Northumbria Healthcare and  
24 Trust?

25 Q. Yes.

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2 A. I know that the thromboprophylaxis medication of  
3 choice was changed from tinzaparin to -- sorry, from  
4 rivaroxaban back to tinzaparin. I know that bleeding was  
5 the primary concern for that change. I am not sure if there  
6 was any component of that change that was related to  
7 infection. I don't know.

8 Q. If Mr. Reed told you that the change was due to  
9 increased wound bleeding, would you have any reason to doubt  
10 Mr. Reed's understanding?

11 A. I'd have no reason to doubt that, no.

12 (Exhibit 20 marked for identification)

13 Q. Have you seen this paper before?

14 A. I may have done. When is it from? 2012. It is  
15 likely that I've seen this before, but I don't remember the  
16 details of it.

17 Q. Do you see, at the top of the paper, one of the  
18 authors is Mr. Mike Reed?

19 A. I do.

20 Q. And another is Simon Jameson, who I believe was a  
21 colleague of sorts to you at one particular time, or was  
22 also a trainee at NHS?

23 A. I have heard the name before. I believe he was --  
24 well, I've heard the name before. I have not, to my  
25 recollection, worked with Simon Jameson before.



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2 Q. Okay. What journal was this published in?

3 A. The Journal of Bone and Joint Surgery American  
4 edition, or --

5 Q. So is this the American counterpart to the British  
6 version that the McGovern study was published in?

7 A. It is. They now are named -- or the British one is  
8 now named differently. Its name has changed, but these  
9 are -- this is the American Journal of Bone and Joint  
10 Surgery -- journal, yes.

11 Q. And this is a peer-reviewed publication; correct?

12 A. It is.

13 Q. And the reviewers have expertise in the field in  
14 determining whether particular articles such as this should  
15 be published in the journal; correct?

16 A. Yes.

17 Q. If we could look at the introduction on page 1555.  
18 In the right-hand column, last full paragraph says:

19 "The aim of the present multicenter study,  
20 based on prospectively collected national data, was to  
21 evaluate the surgically relevant complications of using  
22 either rivaroxaban or an LMWH as thromboprophylaxis.  
23 These complications included wound complications,  
24 readmission, and return to surgery for deep infection  
25 as well [as] the incidents of major bleeding and VTE.

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2 We believe this [is the] first study to describe the  
3 impact of using rivaroxaban for patients undergoing hip  
4 or knee arthroplasty across the English NHS."

5 Do you see that?

6 A. Yes.

7 Q. So to be clear, this study involved hip and knee  
8 arthroplasties; correct?

9 A. That is what this states.

10 Q. And two different types of thromboprophylaxis were  
11 evaluated, one being rivaroxaban and the other a  
12 low-molecular-weight heparin; correct?

13 A. Yes, this is what this appears to say.

14 Q. And the complications included wound complications  
15 in general, versus returns to surgery for deep infection,  
16 among other things; correct?

17 A. That is what this says, yes.

18 Q. If we could now turn to the "Methods" section on  
19 page -- it starts on page 1555 and follows into 1556. The  
20 left-hand column at the bottom begins:

21 "The primary outcome measure was wound  
22 complications (including hematoma, superficial wound  
23 infection, and deep infections requiring return to  
24 surgery within 30 days of procedure."

25 Do you see that?

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2 A. Yes.

3 Q. And now, directly under the "Results" section, it  
4 states:

5 "During the study period, 2762 patients  
6 received rivaroxaban and 10,361 received  
7 a [low-molecular-weight heparin] (Table 1)."

8 A. Sorry, I've lost you.

9 Q. On the same page as what we just read, which is  
10 page 1556, under the section entitled "Results", which is in  
11 the bottom right-hand column of the page.

12 A. Yeah, yeah. Seen.

13 Q. You see that?

14 A. Yeah.

15 Q. And it directs us to Table 1; correct?

16 A. Yes.

17 Q. And if we look at Table 1, that involves patient  
18 demographics on the other page; correct?

19 A. Yes.

20 Q. And sorry to make you switch again, but if we go  
21 back to Table 2, Table 2 is entitled "Complications  
22 Following Lower Limb Arthroplasty"; correct?

23 A. It is.

24 Q. And the first entry is "Total wound complications"?

25 A. It is.

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2 Q. And the data shows a P value of 0.005?

3 A. Yes.

4 Q. Which is statistically significant; correct?

5 A. That would be the implication from this data, yes.

6 Q. And that signifies that there was a statistically  
7 significant difference in the percent of infections among  
8 those patients who received a low-molecular-weight heparin  
9 versus those who received the rivaroxaban?

10 A. That is my understanding of this data and its  
11 interpretation, yes.

12 Q. In the third line there is data corresponding to  
13 return to surgery for infection; correct?

14 A. Yes.

15 Q. And for the low-molecular-weight heparin group, the  
16 percent of infection was 0.53; correct?

17 A. The ... yes.

18 Q. For the rivaroxaban group, the corresponding rate  
19 was 0.62 percent; correct?

20 A. Yes, yes.

21 Q. And the P value was 0.586; correct?

22 A. That's what this data shows, yes.

23 Q. And that P value is not statistically significant,  
24 unlike the P value for total wound complications; correct?

25 A. I would agree that that is what this appears to

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2 say.

3 Q. So this paper, based on this data, shows that there  
4 is not a difference in infection rates between the use of  
5 rivaroxaban and low-molecular-weight heparins; correct?

6 A. This data appears to show that there was no return  
7 to surgery for infection between the low-molecular-weight  
8 heparin and the rivaroxaban group that was statistically  
9 significant for the data. That's what it appears to show.

10 Q. Okay. And the returns to surgery specifically  
11 involved orthopedic procedures; correct?

12 A. Lower limb arthroplasty, yes. These are orthopedic  
13 procedures.

14 Q. And just to be clear, tinzaparin is  
15 a low-molecular-weight heparin; correct?

16 A. That is correct.

17 Q. We'll look at one more study. I guess one last  
18 question is we've established that Mr. Reed is an author of  
19 this paper; correct?

20 A. Yes.

21 Q. You would have no reason to doubt the data  
22 presented in this paper; correct?

23 A. I would not.

24 (Exhibit 21 marked for identification)

25 Q. This study is entitled -- I guess I should say this

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2 paper is entitled "Return to theatre following total hip and  
3 knee replacement, before and after the introduction of  
4 rivaroxaban"; correct?

5 A. Yes.

6 Q. The first author is C Jensen?

7 A. That's right.

8 Q. And the fourth author is M.R. Reed?

9 A. That's correct.

10 Q. That is Mr. Mike Reed; correct?

11 A. That is correct.

12 Q. Again, you have no reason to doubt Mr. Reed's  
13 publications; correct?

14 A. That's correct.

15 Q. In the abstract of the paper -- actually, I'm going  
16 to ask you this first: was this published in the British  
17 version of Bone and Joint Surgery or the American version?  
18 Can you tell?

19 A. This is the British version.

20 Q. And that's the same publication that you studied  
21 your first author paper?

22 A. This is the same publication that I was published  
23 in before that study, yes.

24 (Reporter clarification.)

25 A. This is the same publication that the previous

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2 study was published in -- my previous study was published  
3 in. Sorry.

4 Q. The third sentence of the abstract states:

5 "This study of 1048 total hip/knee  
6 replacements records the rate of return to theatre and  
7 infection before and after the change from a low  
8 molecular weight heparin (tinzaparin) [I said it  
9 incorrectly] to rivaroxaban as the agent of chemical  
10 thromboprophylaxis in patients undergoing lower-limb  
11 arthroplasty."

12 Do you see that?

13 A. I do.

14 Q. "During a period of 13 months, 489 consecutive  
15 patients undergoing lower-limb arthroplasty received  
16 tinzaparin and the next 559 consecutive patients received  
17 rivaroxaban as thromboprophylaxis."

18 Do you see that?

19 A. I do.

20 Q. If we could now turn to page 523, in the bottom  
21 right-hand corner, and the left-hand column which is  
22 entitled "Results"?

23 A. Mm, yes.

24 Q. The third paragraph states:

25 "Of those patients who returned to theatre,

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2 microbiology results showed that five of nine (55.5%)  
3 in group 1 had a deep infection, compared with 14 of 22  
4 (63.6%) in group 2 ( $p=0.7$ )."

5 A. That's what this says, yes.

6 Q. Based on the abstract we read, is it clear that  
7 group 1 refers to patients who received one type of  
8 thromboprophylaxis, whereas group 2 received another type?

9 A. Not from the abstract, but it is from the methods  
10 section --

11 Q. Second paragraph?

12 A. Yeah. Yeah, it is clear that group 1 is the  
13 tinzaparin group and group 2 is the rivaroxaban group. Yes.

14 Q. And in the paragraph that I just recited, the  
15 P value for the differences in returns to theater for  
16 infection was 0.7; correct?

17 A. Where are we?

18 Q. Um, the third paragraph of the results column?

19 A. Yes. That is of the patients who returned to  
20 theater. Yeah, it does not show a statistically significant  
21 difference between the group, according to this sentence --  
22 between the groups.

23 Q. So, in other words, based on the data presented  
24 here, there was no statistically significant difference in  
25 infections between patients who received rivaroxaban



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2 compared to patients who received tinzaparin; correct?

3 A. That is what that sentence appears to say. I would  
4 normally want to read and digest the whole paper before  
5 drawing conclusions from it, but that is what that result  
6 reports, to my understanding.

7 Q. And in the McGovern study, as we talked about five  
8 minutes ago, there was similarly a change between  
9 rivaroxaban and tinzaparin; correct?

10 A. Yes, there -- I believe that during the course of  
11 the data collection -- or the monitored period, rather,  
12 there was a change between thromboprophylactic medications.

13 Q. Based on the data that Mr. Reed has presented in  
14 the paper first authored by Jensen, and the second paper we  
15 discussed, which was first authored by Jameson ...

16 A. Yes.

17 Q. ... does that data show that the change in  
18 thromboprophylaxis from tinzaparin to rivaroxaban and back  
19 to tinzaparin was a confounding factor in the study?

20 A. Could you repeat the question, please?

21 Q. Are you able to read it back?

22 (Record read.)

23 A. This data does not, in my opinion, show that -- or  
24 does not, in my opinion, confirm or deny that either of  
25 these -- that the change in thromboprophylaxis was or was

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2 not a confounding factor.

3 Q. So, if the data shows in these two papers that  
4 there was no statistically significant difference between  
5 returns to theater for infections in orthopedic replacement  
6 surgeries between rivaroxaban and tinzaparin, how could the  
7 change in thromboprophylaxis still be a confounding factor  
8 with respect to infection rates?

9 MR. C. GORDON: Object to the form of the  
10 question.

11 A. A confounding factor is something which could alter  
12 infection rates. And this data, in my opinion, reduces the  
13 chance that this is due to infection rates, but it does not  
14 eliminate this as a confounding factor. These two papers  
15 provide evidence that suggest that rivaroxaban did not, in  
16 these -- for these series of patients, increase infection  
17 rates; and so the data is likely to be relevant to our  
18 reading of the paper in question, the bubble experiment.  
19 They are relevant, and in my opinion would reduce the  
20 likelihood that the change in thromboprophylaxis altered  
21 infection rates, but do not eliminate it as a possible  
22 confounding factor.

23 BY MR. SACCHET:

24 Q. If the data presented in these two factors reduces  
25 the likelihood that the change in thromboprophylaxis was

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2 a confounding factor, would there be any reason to deselect  
3 patients from the population of persons who were presented  
4 in your McGovern study?

5 A. No, I --

6 Q. To, you know, eliminate those who received one  
7 thromboprophylaxis versus those who received a different  
8 thromboprophylaxis?

9 MR. C. GORDON: Object to the form of the  
10 question.

11 A. No, in my opinion it would not be necessary or  
12 appropriate to exclude those patients in the sort of study  
13 that was performed. I remain of the opinion that it was  
14 appropriate to include those patients in that study, and for  
15 the data to be presented as it was in that study.

16 BY MR. SACCHET:

17 Q. Yesterday you were also asked about other  
18 intervention measures that may or may not have occurred as  
19 part of an SSI bundle implemented at NHS; correct?

20 A. At Northumbria Healthcare NHS Trust, yes.

21 Q. One of those suggestions from the deposition  
22 yesterday was that there might have been a change in  
23 dressing?

24 A. Oh, the wound dressing? Yes.

25 Q. And particularly, there might have been a change to

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2 a jubilee dressing?

3 A. There was, at some point, a change to the jubilee  
4 dressing, in my recollection, yes.

5 (Exhibit 22 marked for identification)

6 Q. This is a paper entitled "A prospective randomised  
7 study comparing the jubilee dressing method to a standard  
8 adhesive dressing for total hip and [total] knee  
9 replacements," authored by Neil G. Burke and others;  
10 correct?

11 A. Yes, that is correct.

12 Q. Have you ever seen this paper before?

13 A. I may have seen it, but I don't remember. It is  
14 likely I looked at it, but -- in fact I think I have seen  
15 this paper before, but it was quite a long time ago.

16 Q. Okay. Let's take a look quickly at the method as  
17 described in the abstract on the first page. It states:

18 "124 patients (62 total hip replacements and 62  
19 total knee replacements) were randomly selected to have  
20 either a standard adhesive dressing or a jubilee method  
21 dressing. The number of dressing changes, incidence of  
22 blistering, leakage, appearance of inflammation,  
23 infection rate and the average stay in hospital was  
24 recorded for each patient."

25 Do you see that?

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2 A. I do.

3 Q. So one of the variables that was considered was  
4 infection rate, was it not?

5 A. Yes.

6 Q. And that was determined based on whether a standard  
7 dressing was used or a jubilee dressing was used; correct?

8 A. Those were the two variables that were examined in  
9 this study from how I read this, yes.

10 Q. And if you would turn to internal page 86, which is  
11 the third page, in the left-hand column in the first full  
12 paragraph it begins "Table 1"; do you see that?

13 A. I do.

14 Q. Approximately halfway down there is a statement  
15 that says: "No patients developed a deep infection." Do you  
16 see that?

17 A. I do see that.

18 Q. And now if we direct our attention to Table 1 at  
19 the top of that page, the title of that table bears the  
20 label "Wound complications and number of dressing changes  
21 for the two different types of dressing." Correct?

22 A. Yes.

23 Q. And we see the jubilee dressing is in the middle of  
24 that table, and next to that is the standard adhesive  
25 dressing; correct?

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2 A. Yes.

3 Q. On the left are the different complications that  
4 may have arisen as a result of, I guess you could say that  
5 analyzed whether there was significance between the two  
6 dressings; correct?

7 A. Yes.

8 Q. The fourth one down states "Infection"; correct?

9 A. Yes.

10 Q. And for jubilee dressing there was a 0 percent  
11 infection rate?

12 A. In these data, yes.

13 Q. And in these data, there was a 0 percent infection  
14 rate with respect to standard adhesive dressings; correct?

15 A. Yes.

16 Q. The two percents of infection were the same;  
17 correct?

18 A. In these data, yes.

19 Q. When you have two values of zero, there is no  
20 statistical significance; correct?

21 A. You can't state that there is a statistical  
22 significance, because there is no difference and there's no  
23 data to state that.

24 Q. Based on that understanding of this paper, and the  
25 data presented therein, does this study show that the change

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2 in jubilee dressing that occurred during the time in which  
3 the data was collected for the McGovern study impacted  
4 infection rates?

5 MR. C. GORDON: Object to the form of the  
6 question: lack of foundation, incomplete hypothetical.

7 A. It's not possible to say, in my opinion. The  
8 numbers in this study are too small. You have a number of  
9 patients that is 124, and the numbers are too small to be  
10 able to draw a meaningful conclusion in terms of infection,  
11 with regard to these two variables, in my opinion.

12 BY MR. SACCHET:

13 Q. So if I could point out, to the extent that this  
14 would change your mind, the asterisks which are denoted in  
15 the right-hand column of the standard adhesive dressing  
16 column; do you see those?

17 A. Yes.

18 Q. And a single asterisk stands for a P value of less  
19 than 0.05; correct?

20 A. Mm-hm, yes.

21 Q. And a double asterisk stands for a P value of 0.01  
22 and less?

23 A. Yes.

24 Q. And three asterisks stands for a P value of 0.001  
25 or less; correct?

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2 A. Yes.

3 Q. The infection row has no such asterisk in it,  
4 does it?

5 A. That's correct.

6 Q. So, because we established earlier that statistical  
7 significance begins at 0.05, which is a single asterisk ...

8 A. Right.

9 Q. ... presumably this 0 percent infection rate, the  
10 difference between 0 and 0 is non-significant; correct?

11 A. No, that's not how I would interpret this. There  
12 is no data to draw a meaningful conclusion from. You need  
13 to have some data, by my understanding, to be able to draw  
14 a conclusion of statistical significance. You can't comment  
15 on whether these data are statistically significant. If one  
16 were designing this study purely to look at infection rates  
17 between the two dressings, it is likely that the study would  
18 need to include more patients and the study -- and to ensure  
19 it was sufficiently powered to be able -- "powered" meaning  
20 to have enough patients in it -- to see enough infections to  
21 be able to draw a meaningful conclusion.

22 The fact that there were no infections in 124  
23 patients is not surprising, because infection rates are  
24 generally low. This is a problem of research in this  
25 area. Because infection is rare, thankfully, you need



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2 large numbers of patients in studies to see if one  
3 intervention has a difference with another  
4 intervention, in terms of infection rates. In my  
5 opinion, this study does not demonstrate superiority of  
6 one adhesive dressing over another, purely in terms of  
7 infection.

8 Q. Fair enough --

9 A. It may for other conditions, such as blistering and  
10 leakage, but for infection -- because those are more  
11 common -- consequences post-operation, and the study appears  
12 to have been adequately powered to identify those  
13 differences and state statistical significance. But for  
14 infection, there were not enough incidences of infection to  
15 be able to draw meaningful conclusions, or a difference  
16 between the two.

17 Q. Are you aware of any paper that is adequately  
18 powered that shows that a change from a standard adhesive  
19 dressing to a jubilee dressing would statistically  
20 significant -- significantly alter infection rates among  
21 arthroplasties?

22 A. I am not aware of any such paper.

23 Q. Are you aware of any published papers that  
24 suggest -- I should say that find statistically significant  
25 differences between joint infection rates from the use of

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2 MSSA screening versus non-screening?

3 A. Sorry, could you say that again, please?

4 Q. Are you aware of any evidence that is statistically  
5 significant that suggests that the use of MSSA screening  
6 significantly impacts the rate of deep joint infections  
7 among patients?

8 A. I'm not aware of any such papers.

9 Q. Are you aware of any evidence that pre-warming,  
10 when used in combination with intraoperative warming,  
11 significantly impacts deep joint infection rates among  
12 patients?

13 A. I am not aware of papers which provide evidence of  
14 that.

15 Q. Have you seen an article by Mr. Reed and another  
16 individual, bearing the last name Refaie, which analyzed the  
17 NHS SSI bundle?

18 A. I presume you mean Northumbria Foundation Trust.  
19 I am aware that Mr. Reed and Mr. Refaie have done research  
20 together. I may have seen such paper but I don't remember.

21 Q. Do you recall Mr. Reed, in that paper, making the  
22 statement: "A switch to the alternative conductive fabric  
23 warming led to a significant decrease in deep joint  
24 infections"?

25 A. I -- that statement sounds familiar but I don't

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2 remember reading it in a paper.

3 Q. Would you have any reason to doubt, if Mr. Reed  
4 made such a statement, the accuracy of such a statement?

5 MR. C. GORDON: Object to the form of the  
6 question: lack of foundation, assumes facts not in evidence.

7 A. If Mr. Reed indeed made that statement in a paper,  
8 I'd have no reason to doubt the veracity of that statement.

9 BY MR. SACCHET:

10 Q. Are you aware of the fact that after the McGovern  
11 paper was published in the Journal of Bone and Joint  
12 Surgery, that additional data supported an elevated  
13 odds-risk ratio?

14 MR. C. GORDON: Object to the form of the  
15 question: assumes facts not in evidence, incomplete  
16 hypothetical.

17 A. I was not.

18 BY MR. SACCHET:

19 Q. Okay.

20 (Exhibit 23 marked for identification)

21 Q. That's an e-mail entitled "Full workup of the stats  
22 you requested"; correct?

23 A. Yes.

24 Q. And there is an e-mail from Mr. Albrecht to  
25 Mr. Reed, and you are cc'd on the e-mail on November 29,

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2 2011; correct?

3 A. Yes.

4 Q. And there is an attachment called "Results";  
5 correct?

6 A. Yes.

7 Q. And if you turn the page, there is a table. Does  
8 this table resemble the table in the published McGovern  
9 study?

10 A. It does resemble it. I'll check if it is the same.

11 Q. There are different data points, but just in terms  
12 of the style and form of the table?

13 A. Err ...

14 Q. It is exhibit 13, to make sure you're on the right  
15 one.

16 A. I'm there. I'm on exhibit 13. Which table are you  
17 referring to? Table 1 in exhibit 13?

18 Q. I am looking at -- yes. No.

19 A. Table 2.

20 Q. Yeah, the lower half of Table 2. I mean with parts  
21 of the lower half, as well.

22 A. Yes, I would agree this is similar in form to part  
23 of Table 2 in what you refer as to the "McGovern paper".

24 Q. Okay. And if we look at that table in the e-mail  
25 thread, for a conductive fabric, number developing

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2 infection, 7; correct?

3 A. Oh, yes.

4 Q. Number not developing infection, 792; correct?

5 A. Yes.

6 Q. For a total population of 709 patients who received  
7 conductive fabric warming; correct?

8 A. Yes.

9 Q. That number is significantly larger than the total  
10 population of individuals who received conductive fabric  
11 warming in the final published paper, exhibit 13; correct?

12 A. That number is larger. To say it was significantly  
13 larger would require a statistically significant test. So  
14 be careful about using the words "statistically  
15 significantly", but it is a larger number.

16 Q. How about double?

17 A. Let's see. Conductive fabric 792 versus 368. Yes,  
18 I think that's a reasonable thing to say.

19 Q. Okay. And if we go back to the text of the e-mail,  
20 Mr. Reed writes back to Mr. Albrecht and copies you in and  
21 says, in the last line of the first paragraph:

22 "You are 3.6 times more likely to get an  
23 infection on FAW than CFW."

24 Do you see that?

25 A. Yes. It phrases a question, but yes.

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2 Q. Yes. Do you have any reason to doubt Mr. Reed's  
3 statement to that effect?

4 A. It appears that Mr. Reed is asking if that is what  
5 the data is showing in this table.

6 Q. And do you see, in the table itself, a demarcation  
7 of 3.6 on the right-hand side of the odds ratio?

8 A. I do.

9 Q. So in fact Mr. Reed was referring to this table;  
10 correct?

11 A. That is -- seems likely.

12 Q. And this table was sent as a results attachment  
13 from Mr. Albrecht?

14 A. Yes.

15 Q. You have no reason to doubt Mr. Albrecht's ability  
16 to conduct statistical analysis of data, do you?

17 A. None whatsoever.

18 Q. You have no reason to doubt that, based on this  
19 patient population of those who received conductive fabric  
20 warming, which is double the size of the patient population  
21 in the McGovern study, that there was a 3.6 odds ratio?

22 A. That is what this data appears -- (overspeaking) --

23 MR. C. GORDON: Object to the form of the  
24 question.

25 THE COURT REPORTER: Sorry, can you repeat the

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2 objection, please.

3 MR. C. GORDON: Form.

4 A. That is what this data appears to show.

5 BY MR. SACCHET:

6 Q. So this data shows there is a 3.6 times increase in  
7 infection as a result of using forced-air warming devices  
8 compared to conductive fabric warming devices; correct?

9 A. That is what --

10 MR. C. GORDON: Object to the form of the  
11 question.

12 A. That is what this table appears to show.

13 BY MR. SACCHET:

14 Q. And both this odds ratio and the odds ratio  
15 presented in the final published McGovern study are both  
16 above 3.0; correct?

17 A. Yes.

18 Q. So, based on this data in the increased patient  
19 population of those who received conductive fabric warming,  
20 this data corroborates the fact that there is at least  
21 a three times more likely chance that patients who received  
22 forced-air warming developed an infection, compared to those  
23 who received conductive fabric warming?

24 MR. C. GORDON: Object to the form of the  
25 question.

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2 A. This data -- I can't agree with the term  
3 "corroborates the fact". The fact is not --

4 BY MR. SACCHET:

5 Q. Also shows?

6 A. Yeah. Could you just repeat the phrase, please, or  
7 rephrase that? Or --

8 Q. I'll rephrase the question.

9 Based on the data presented in this table and the  
10 data presented in the McGovern study, both studies for  
11 both datasets show that there was a three -- at least  
12 a three times more likely chance that a patient  
13 developed an infection after using forced-air warming  
14 than conductive fabric warming?

15 MR. C. GORDON: Object to the form of the  
16 question.

17 A. Yes. Patients who were in the group with  
18 forced-air warming on this data appear to have had a three  
19 times or more higher incidence of infection compared to the  
20 conductive fabric group of patients for this study.

21 THE COURT REPORTER: Can I just ask you to stop  
22 for 30 seconds, sorry.

23 THE VIDEOGRAPHER: Going off at two minutes past  
24 three.

25 (3:02 p.m.)



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2 (Break taken.)

3 (3:04 p.m.)

4 THE VIDEOGRAPHER: Back on the record at four  
5 minutes past three.

6 (Exhibit 24 marked for identification)

7 BY MR. SACCHET:

8 Q. Mr. McGovern, are you aware of any data that's been  
9 collected regarding other healthcare facilities that have  
10 shown a decreased rate of infection after the switch from  
11 forced-air warming devices to conductive fabric warming  
12 devices?

13 A. I am not.

14 Q. If you could take a look at the exhibit which was  
15 just marked. The first page is an e-mail; is that correct?

16 A. Yes.

17 Q. From Mr. Albrecht to Scott Augustine, bearing the  
18 subject line "Results" with attachments "MA\_edits"; correct?

19 A. Yes.

20 Q. And Mark Albrecht states:

21 "I've updated the statistics in the white  
22 paper under \*\*MA\_edits.doc\*\*."

23 A. Yes.

24 Q. "The updates include:

25 "The statistics in the Table for all centers and

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2 the pooled result[s]

3 "The statistics in the discussion for the updated  
4 McGovern numbers provided as provided [sic] in the  
5 text."

6 Do you see that?

7 A. Yes.

8 Q. In the third paragraph it says:

9 "I think this is the best modeling approach  
10 (i.e. a conservative one) for the data you have,  
11 especially if you expect these results to be critically  
12 questioned down the road."

13 Do you see that?

14 A. Yes.

15 Q. Okay. And the next page is a document entitled  
16 "Forced-air warming link to periprosthetic total joint  
17 replacement infections"; correct?

18 A. Yes.

19 Q. And the "Methods" says:

20 "To investigate whether the rising  
21 contaminants from the waste FAW heat are linked to  
22 PJIs, we retrospectively collected joint implant  
23 infection data from three hospitals. We compared PJI  
24 rates during a period of forced-air warming to PJI  
25 rates during a period of free-air conductive fabric

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2 warming. Surgical and antibiotic protocols were held  
3 constant."

4 Do you see that?

5 A. I see that.

6 MR. C. GORDON: I'm going to object on foundation  
7 grounds to any questions about this, unless it is  
8 established that he did in fact write it, as it indicates on  
9 it.

10 MR. SACCHET: My questions won't pertain to  
11 Mr. McGovern's contribution to this study or not.

12 BY MR. SACCHET:

13 Q. This document was attached to the e-mail from  
14 Mr. Albrecht to Mr. Augustine; correct?

15 MR. C. GORDON: Objection: lack of foundation.

16 A. There's no way for me to know if that's the case.

17 BY MR. SACCHET:

18 Q. Do the Bates numbers in the bottom right-hand  
19 corner follow one another?

20 A. They are sequential numbers, yes.

21 Q. Assuming that this document was attached to the  
22 cover e-mail, does it appear that Mr. Albrecht analyzed the  
23 statistics presented in this document?

24 MR. C. GORDON: Objection: lack of foundation.

25 A. If these documents are indeed related, it would be

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2 reasonable to assume that Mr. Albrecht is referring to this  
3 document, but I've no way of verifying if that's the case.

4 BY MR. SACCHET:

5 Q. And that's why I ask for the assumption.

6 A. If we're assuming that, then we'll assume that.

7 Q. And you have no reason to doubt Mr. Albrecht's  
8 ability to analyze data; correct?

9 MR. C. GORDON: Same objection.

10 A. That's correct.

11 BY MR. SACCHET:

12 Q. If we could turn to page 3 in the Results section,  
13 there is a table; do you see that?

14 A. Yes.

15 Q. And Center 1 says "Patient Warming Device" and  
16 under that there's "Conductive Fabric and Forced Air". Do  
17 you see that?

18 A. I do.

19 Q. And in the columns there are four labels: "No.(%)  
20 Developing Infection", "No.(%) Not Developing Infection",  
21 "Odds Ratio" and "P value"; do you see that?

22 A. I see that.

23 Q. For Center 1, in conductive fabric warming, based  
24 on this dataset, it appears that two persons developed an  
25 infection; correct?

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2 MR. C. GORDON: Objection: lack of foundation.

3 MR. SACCHET: I said based on this dataset.

4 MR. C. GORDON: Same objection.

5 A. I haven't read the results or methods of this  
6 paper, so at the moment all I can see is that a number 2 is  
7 next to a row heading "Patient Warming Device Conductive  
8 Fabric" in a cell whose column is "No. Developing  
9 Infection", but I don't know what this refers to because  
10 I don't recall ever seeing this before.

11 BY MR. SACCHET:

12 Q. And next to that, there is a number -- I should say  
13 underneath that, there is a number 6; do you see that?

14 A. A number 6, yes. I see the number 6.

15 Q. And it appears that that number 6 corresponds to  
16 the label "Forced air" and "No.(%) Developing Infection";  
17 correct?

18 A. The number 6 is within the cells with those labels,  
19 yes.

20 Q. So it appears, based on this table and the way that  
21 it has been formatted, that two patients who received  
22 conductive fabric developed an infection, whereas six  
23 patients who received forced-air warming developed an  
24 infection?

25 MR. C. GORDON: Objection: lacks of foundation.

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2 Also, this goes pretty far beyond the fact witness  
3 limitation.

4 A. I can't make that statement because I have not read  
5 the rest of the paper, and I -- this doesn't -- numbers in a  
6 table does not let me say that patients have received one  
7 thing or another. I need more information to be able to  
8 make that statement.

9 BY MR. SACCHET:

10 Q. Okay, let's look at the page 4 in the "Discussion"  
11 section.

12 A. Page 4 in the "Discussion" section. Okay.

13 Q. The fourth paragraph, second line, says:

14 "The FAW patients who received the first  
15 antibiotic were drop from the results. This left 677  
16 patients with 22 PJIs in the FAW group receiving the  
17 second antibiotic (3.2% PJI rate). Then 14 more months  
18 of CFW patients were added for a total of 1097 CFW  
19 patients, which included 10 PJIs, all of whom received  
20 the second antibiotic."

21 A. That's what it says.

22 Q. "These new data show that the PJI rates decreased  
23 72% when FAW was discontinued and CFW initiated," totaling  
24 1774 patients with a P value of 0.004.

25 Do you see that?

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2 A. This says "0.0004", but I see that, yes.

3 Q. "This 72% reduction compares favorably with the  
4 previously reported 74% reduction, indicating that the  
5 switch in antibiotics was not a significant variable."

6 Do you see that?

7 A. I see that.

8 Q. If this data was presented by Mr. Albrecht, would  
9 you have any reason to doubt it?

10 MR. C. GORDON: Object to the form of the  
11 question. Also lack of foundation, incomplete hypothetical,  
12 and assumes facts not in evidence.

13 A. This data is not interpretable by me at the moment  
14 because I have not read the paper. Data in isolation  
15 doesn't mean anything to me, so I can't make any comment on  
16 that data.

17 BY MR. SACCHET:

18 Q. Fair enough. Based on what we reviewed, the data  
19 presented in your paper, the McGovern paper ...

20 A. Yes.

21 Q. ... and the follow-up data that we reviewed, which  
22 Mr. Reed had commented on ...

23 A. Yes.

24 Q. ... do you have any doubt that the study period  
25 analyzed in the McGovern study recorded a 3.8 odds risk

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2 ratio?

3 MR. C. GORDON: Object to the form of the  
4 question.

5 A. The study data reported that odds ratio.

6 BY MR. SACCHET:

7 Q. And that data shows that there is a 3.8 more likely  
8 chance of developing a deep joint infection from the use of  
9 forced-air warming, compared to conductive fabric warming?

10 A. It showed that the odds ratio for these patients in  
11 these circumstances for this data was 3.8. That's what that  
12 showed. It did not necessarily show there was a higher  
13 chance; it just showed that that is what happened.

14 MR. SACCHET: OK. Do we need a break, or are we  
15 okay? Why don't we take one now, because I'm going into  
16 a new section.

17 THE VIDEOGRAPHER: Going off the record at  
18 thirteen minutes past three.

19 (3:13 p.m.)

20 (Break taken.)

21 (3:21 p.m.)

22 THE VIDEOGRAPHER: Back on the record at  
23 twenty-one minutes past three.

24 BY MR. SACCHET:

25 Q. Mr. McGovern, we're going to transition to what has



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2 been previously marked as exhibit 8. And again, put  
3 essentially everything else to the side.

4 A. Okey dokey.

5 Q. Okay. Beyond the first page, the second page  
6 begins a copy of a study entitled "Forced-Air Warming  
7 Design: Evaluation of Intake Filtration, Internal Microbial  
8 Buildup, and Airborne Contamination Emissions."

9 MR. C. GORDON: What page are you on?

10 MR. SACCHET: I am on 275, internal Bates number  
11 3MBH00107864. Exhibit 8.

12 MR. C. GORDON: The binder?

13 MR. SACCHET: No. This is my binder.

14 MR. C. GORDON: I'm sorry, which exhibit was it?

15 MR. SACCHET: Exhibit 8.

16 A. I can see that.

17 BY MR. SACCHET:

18 Q. This article was co-authored by Mr. Reed,  
19 Mr. Kimberger, yourself and Mr. Albrecht; correct?

20 A. Correct.

21 Q. And if we could turn to the "Methods" section of  
22 the paper, which is still on that same page.

23 A. Yes.

24 Q. There are a number of boldface and italicized  
25 headings?

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2 A. Yes.

3 Q. The second one says: "Intake Filter Efficiency".

4 A. Yes.

5 Q. On the next page there's one entitled "Intake  
6 Filter Performance in the Operating Theater"?

7 A. Yes.

8 Q. And the third is entitled "Generation of airborne  
9 Contamination"?

10 A. Yes.

11 Q. These were the three variables that you examined in  
12 this study; correct?

13 A. Yes.

14 Q. And you examined a Bair Hugger model 750; correct?

15 A. That is what I understand was examined in this  
16 study, yes.

17 Q. And if you refer to internal page 275, the  
18 right-hand column at the top says:

19 "Prior research has rated the intake  
20 filtration efficiency of legacy FAW devices  
21 (Bair Hugger 505) at 93.8% for a 'older' filter model  
22 in clinical use (200708C) and 61.3% for a 'newer'  
23 filter model (200708D) scheduled to replace the older  
24 filter in clinical use."

25 Correct?

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2 A. Yes.

3 Q. Do you know what study that refers to?

4 A. It refers to the study that we were discussing  
5 earlier.

6 Q. Let's look at footnote 3, which is the citation to  
7 that proposition. Are you on page 280 internal?

8 A. Yes.

9 Q. And footnote three bears the names: Albrecht,  
10 Gauthier, Belani, Litchy, Leaper. Title: "Forced-air  
11 warming blowers: an evaluation of filtration adequacy and  
12 airborne contamination emissions in the operating room."

13 Do you see that?

14 A. Yes.

15 Q. Published in the American Journal of Infection  
16 Control; correct?

17 A. Yes.

18 Q. We haven't talked about that paper yet today, have  
19 we?

20 A. Haven't we? No, we must not have.

21 Q. Are you familiar with that paper by Mr. Albrecht?

22 A. Yes, I've seen it before.

23 Q. And as stated in the paragraph we just read, that  
24 study, based on the citation in this paper that you were  
25 co-author of, found that the old filter was 93.8 percent

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2 efficient, whereas the newer filter was 61.3 percent  
3 efficient for the model 505; correct?

4 A. Yes, we were discussing filtration efficiencies at  
5 61.3 percent of the 57 today, were we not?

6 Q. Yes, but we were actually looking at this same  
7 study, the --

8 A. This study? Right, okay. Sure, okay.

9 Q. And now bringing us back to this study, under  
10 "Intake Filter Efficiency" in the "Methods" section at the  
11 bottom of 275 it says:

12 "New intake filters were acquired from the  
13 manufacturer, which was measured by challenging the  
14 filters with sodium chloride particulate" --

15 A. Sorry, I've lost that.

16 Q. On the carryover paragraph.

17 A. Yes, "New intake filters were acquired ..." Yes.

18 Q. So, just to be sure, you tested new intake filters  
19 for filter efficiency?

20 A. That's what was tested in this study, yes.

21 Q. Okay. And with respect to the next title in bold  
22 and italics, it says, "Intake Filter Performance in the  
23 Operating Theater"; do you see that?

24 A. Yes.

25 Q. And it says:

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2 "Twenty-three FAW blowers, in a single hospital in  
3 Vienna, Austria, were sampled after-hours in the  
4 operating theaters to quantify the performance of the  
5 intake filter in the clinical environment."

6 A. Yes.

7 Q. And finally, for the next heading, "Generation of  
8 Airborne Contamination" it states:

9 "The filters were replaced, and these same 23  
10 FAW blowers were sampled for generation of airborne  
11 contamination, which was determined by comparing  
12 observed particle counts in the airstream exiting the  
13 FAW blower with what would be predicted based on the  
14 measured filtration efficiency of each intake filter.  
15 Specifically, we measured particle counts greater than  
16 0.3 micron in the intake and distal airstreams."

17 Do you see that?

18 A. Yes.

19 Q. Okay, so those are the methods in this paper that  
20 you co-authored; correct?

21 A. Yes.

22 Q. Okay. Turning to the results of this paper on  
23 internal page 277. In the first paragraph, regarding  
24 "Intake Filter Retention Efficiency", we see:

25 "The mean efficiency for intake filter models

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2 75093D (n=5) was found to be 63.8% at the MPPS of 0.2 $\mu$ m  
3 (Figure 1) using a test method in accordance with [the]  
4 ventilation industry standards."

5 Do you see that?

6 A. Yes.

7 Q. Do you have any reason to doubt the accuracy of  
8 that conclusion?

9 A. No.

10 Q. Based on the Figure 1 directly above that, the 63.8  
11 percent figure is specifically denoted on the graph;  
12 correct?

13 A. Yes.

14 Q. And to the right of that graph, the size of the  
15 particles increases in terms of diameter; correct? On the X  
16 axis?

17 A. Yes.

18 Q. For -- there are specific points in the dataset  
19 between 0.1 and 1, correct?

20 A. Yes.

21 Q. That are labeled on this graph?

22 A. There are.

23 Q. And for both of those data points between 0.1 and  
24 1, their retention efficiency is below 80 percent; correct?

25 A. Correct.

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2 Q. And beyond 1.0, there are also two discrete data  
3 points between 1.0 and 10.0; correct?

4 A. There are two discrete data points between 1.0 and  
5 10.0, yes.

6 Q. And for both of those data points, the retention  
7 efficiency percentage is less than 90 percent?

8 A. Yes.

9 Q. Do you have any reason to doubt the accuracy of the  
10 data presented in Figure 1?

11 A. I do not.

12 Q. Based on the data presented in Figure 1, would it  
13 be fair to state that for particles sized 0.1 to 10 microns  
14 in diameter, that 10 percent of microns, 10 percent of  
15 particles could pass through the filter, at least?

16 MR. C. GORDON: Object to the form of the  
17 question: lack of foundation.

18 A. I think that's a reasonable assertion to state  
19 based on this data. I believe that is what this chart  
20 displays.

21 BY MR. SACCHET:

22 Q. And in some cases, with respect to the most  
23 penetrating particle size of 63.8 percent, more than 30  
24 percent of particles of that size would pass through the  
25 filter?

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2 MR. C. GORDON: Same objection.

3 A. That is what I understand from this data, yes.

4 BY MR. SACCHET:

5 Q. As we've established earlier today, you're not  
6 aware of any other filters on a model 750 Bair Hugger than  
7 the one at the intake; correct?

8 A. That is correct. I'm not aware of any other  
9 filters.

10 Q. Now let's take a look at the section of the results  
11 entitled "Airborne Contamination Emissions in the Operating  
12 Theater."

13 A. Okay.

14 Q. In the second paragraph of that section, which is  
15 the first paragraph in the right-hand column, it states:

16 "Distal hose end air stream particle  
17 emissions were well above what would be expected for  
18 most FAW blowers (n=22) based on intake filter  
19 performance (Figure 2); 96% of FAW blowers were  
20 generating significant levels of contamination greater  
21 than 0.3  $\mu$ m in size."

22 Do you see that?

23 A. I do.

24 Q. Do you have any reason to doubt the accuracy of  
25 that finding?



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2 A. It says 96 percent of FAW blowers, the number of  
3 the 22. Yeah, so that would mean that all but one were  
4 generating -- is that right? Four, five -- yeah. No,  
5 I don't have any reason to doubt that.

6 Q. The statement continues:

7 "These FAW blowers were generating up to  
8 110,000 particles per cubic foot downstream of the  
9 intake filter, which [is] at an airflow of 1,274 liters  
10 a minute [or] (45cu feet per minute) translates to  
11 82,500 particles per second being emitted from the FAW  
12 blower hose end."

13 Do you see that?

14 A. I do see that.

15 Q. And if we look at Figure 2 on the next page, as one  
16 example of one of the forced-air warmers that was evaluated  
17 in this study, specifically forced-air warmer blower ID 14,  
18 which is on the right-hand side of that graph.

19 A. Yes.

20 Q. That particular blower was generating almost  
21 120,000 airborne particles; correct?

22 A. Yes. It doesn't say how long over ... it mentions  
23 that many particles, but it doesn't say over what period of  
24 the time on the table. No, it is per cubic foot. Yeah, it  
25 does say. Yeah, 120,000 particles of greater than or equal

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2 to 0.3 microns per cubic foot. Yeah, that is what  
3 I understand from that graph, with reference to blower unit  
4 14.

5 Q. And you have no reason to doubt the accuracy of  
6 that finding?

7 A. I do not.

8 Q. In the next paragraph in the "Results" section, do  
9 you see the bold italicized face type bearing the title  
10 "Internal Air Path Microbial Colonization"?

11 A. Where is that?

12 Q. On page 277, internal. The last paragraph in the  
13 right-hand column.

14 A. Yes, yes, I see that.

15 Q. Okay. It says:

16 "Air path swabs revealed the presence of viable  
17 microorganisms in 100% of FAW blowers (Table), with the  
18 heaviest growth reported on the internal air path  
19 surfaces of the elbow. Isolates of coagulase-negative  
20 staphylococci, mold, and micrococci were detected inside  
21 74%, 26% and 9% of FAW blowers respectively."

22 Do you see that?

23 A. I do see that.

24 Q. And the table for that data is presented on  
25 internal page 278 on the right-hand side; do you see that?

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2 A. Yes.

3 Q. Do you have any reason to doubt the findings in  
4 this paper with respect to the internal air path microbial  
5 colonization of the model 750 Bair Hugger devices tested in  
6 this study?

7 A. I do not.

8 Q. Some of the organisms delineated in the table in  
9 page 278 could colonize deep joint infections; correct?

10 A. Yes.

11 Q. Given the low level of filtration, I guess you'd  
12 say the 63.8 percent level of filtration in the devices that  
13 were tested in this study, would you be concerned by  
14 particles passing through the filter to the inside of the  
15 device?

16 MR. C. GORDON: Object to the form of the  
17 question.

18 A. Yes.

19 BY MR. SACCHET:

20 Q. Why?

21 A. Because there is a potential, if particles were  
22 drawn into the device and then were blown out of the device,  
23 that those particles and those bacteria could, in theory, be  
24 drawn towards the patient and then on to the operative site.

25 Q. That's a risk, at least, of using the devices that

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2 were tested in this study; correct?

3 MR. C. GORDON: Object to the form of the  
4 question.

5 A. That is a potential risk.

6 BY MR. SACCHET:

7 Q. And that risk relates to the risk of developing  
8 deep joint infections; correct?

9 A. It may do.

10 Q. And that's because just a single bacterium could  
11 cause a deep joint infection in orthopedic surgeries;  
12 correct?

13 A. A single bacterium can cause a deep joint infection  
14 in orthopedic surgery, yes.

15 Q. On the last page of the study, bearing internal  
16 page number 280, the last paragraph states:

17 "To address the identified design  
18 deficiencies, manufacturers should redesign FAW blowers  
19 to allow for regular cleaning and decontamination in  
20 accordance with the governmental guidelines for  
21 reusable medical equipment."

22 Do you see that?

23 A. I do see that.

24 Q. In your view, and given your training in orthopedic  
25 surgeries, why did you make this recommendation as

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2 a co-author of this study?

3 A. That recommendation is one which I think is  
4 appropriate, given the results of the study, and it was made  
5 because effective cleaning and decontamination of any piece  
6 of equipment in an operating room is, in my opinion,  
7 important to minimize opportunity for bacteria to colonize  
8 any area, be distributed into any part of the operating  
9 room, and therefore minimize the risk of bacteria finding  
10 their way into a place where they shouldn't be, namely the  
11 operative field.

12 Q. So, given that the results of this study which we  
13 just discussed showed that, for the Bair Huggers sampled in  
14 the study, that 100 percent of them had growth of bacteria  
15 inside of the device, would you be concerned about that in  
16 practicing orthopedic surgery?

17 A. Yes.

18 Q. And that's because the bacteria inside of those  
19 devices could make their way to the surgical site?

20 A. Yes.

21 Q. In addition to that statement, in the final  
22 paragraph you go on to say:

23 "Second, inlet filtration could be upgraded  
24 to HEPA quality (99.97% efficient) to prevent microbial  
25 ingress."

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2 Do you see that?

3 A. I do see that.

4 Q. As a coauthor of this paper, why did you make that  
5 recommendation?

6 A. That recommendation was made to minimize the --  
7 well, following that recommendation, would, in theory,  
8 minimize the opportunity for bacteria to gain access to the  
9 internal workings of the blower unit, and therefore minimize  
10 the chance that bacteria could colonize, or even exist,  
11 within the blower unit.

12 Q. And that's because there is also a chance that  
13 those bacteria that might colonize inside the unit could  
14 make their way to the surgical site?

15 A. That is the ultimate concern, yes.

16 Q. And this is especially important in orthopedic  
17 procedures because, again, just a single bacterium could  
18 cause a deep joint infection?

19 A. That is correct. It is important not only to  
20 reduce the opportunity for colonization, but also to reduce  
21 the opportunity for a bacteria to be drawn into the unit not  
22 caught by a filter, and directly to be exhausted from the  
23 unit, as well as the risk of bacteria collecting and  
24 colonizing in an area.

25 Q. And based on these statements that we've just

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2 discussed in this paper, you're aware of the fact that the  
3 Bair Hugger 750, at least, cannot be cleaned inside of the  
4 device?

5 A. I am not familiar with the details of the design of  
6 the Bair Hugger 750, so I don't know how possible it is to  
7 clean the inside of the device. I don't remember.

8 Q. But, I mean, you stand by the statement that the  
9 device should be redesigned to allow for regular cleaning  
10 and decontamination; correct?

11 A. I stand by any recommendation which improves the  
12 likelihood of operating room equipment being appropriately  
13 cleaned.

14 Q. So you stand by the fact that patient safety is of  
15 paramount concern when using a medical device in an  
16 orthopedic surgery; correct?

17 A. Absolutely correct.

18 Q. And one way to improve the safety of the  
19 Bair Hugger device would be to allow for internal cleaning  
20 of the device?

21 A. In my opinion, yes.

22 Q. And another way to do that would be to equip the  
23 Bair Hugger device with a HEPA filter; correct?

24 A. Yes.

25 Q. Are you aware that studies dating back to 1997,

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2 authored by a scientist with the last name Avidan, also  
3 recommended the use of HEPA filtration on Bair Hugger  
4 devices?

5 MR. C. GORDON: Object to the form of the  
6 question, assumes facts not in evidence.

7 A. I was not.

8 (Reporter clarification.)

9 MR. SACCHET: I don't recall the end of the  
10 question, probably because of the speaking objection, so  
11 I'll restate it.

12 BY MR. SACCHET:

13 Q. Are you aware -- well, there's no point. You told  
14 me the answer.

15 THE COURT REPORTER: Can you restate the  
16 objection?

17 MR. C. GORDON: Form, foundation, assumes facts  
18 not in evidence.

19 BY MR. SACCHET:

20 Q. You're not aware that the Bair Hugger has been  
21 equipped with a HEPA filter, are you?

22 A. I was not aware of that, no.

23 Q. Let me now turn to the Belani study. If you could  
24 turn to exhibit 14.

25 A. I presume I've got it somewhere.



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2 Q. I mistakenly told you to put the other exhibits to  
3 the side.

4 A. There it is.

5 Q. All right. This document is a copy of the study  
6 entitled "Patient Warming Excess Heat"; correct?

7 A. Yes.

8 Q. And it was authored by you and Dr. Belani,  
9 Mr. Albrecht, Mr. Reed and Professor Nacathsheim; correct?

10 A. Yes.

11 Q. And it was published in Anesthesia & Analgesia;  
12 correct?

13 A. It was.

14 Q. Okay. Did Mr. Albrecht invite you to participate  
15 in this study?

16 A. Yes.

17 Q. Okay. Did you travel to Minnesota to conduct this  
18 study?

19 A. I did.

20 Q. Did you help design the experiment itself?

21 A. Yes.

22 Q. And there were two parts of this study, one  
23 component involving bubble counts with respect to simulated  
24 knee surgery, and another part involving photos of  
25 convection currents generated by the Bair Hugger; correct?

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2 A. Yes.

3 Q. Let's focus on the simulated knee procedure. On,  
4 if you need it as a reference, internal page 408, the  
5 experimental design of this study was a 2x3 vectorial  
6 design; correct?

7 A. Yes.

8 Q. And like the McGovern study, two of the factors  
9 were a type of warming device, one being the Bair Hugger and  
10 the other being the Hotdog; correct?

11 A. Yes.

12 Q. And the three factors -- actually, I take that  
13 back. The three variables were Hotdog versus Bair Hugger  
14 versus control.

15 A. Oh yes. That's right, yes.

16 Q. And the drape heights were in two forms, one being  
17 low drape and the other being high drape?

18 A. Yes, that's right.

19 Q. Okay. And in this study you examined bubble counts  
20 on -- using a sequence of ten photos at 10-second intervals  
21 for each run; correct?

22 A. Yes.

23 Q. And you determine the number of bubbles reaching  
24 the surgical site by counting the number of bubbles  
25 intersecting a vertical light curtain?

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2 A. Yeah, by -- yes. Yeah, that's right. Well,  
3 counting the number of bubbles within a specified area of  
4 a photo frame, I think. Yeah.

5 Q. Okay. Dr. Belani was present during the  
6 simulation; correct?

7 A. He was present for some parts of the simulation.  
8 If he was present for 100 percent of the time, but he was  
9 there present while the spent was being set-up and taking  
10 place.

11 Q. And he is an experienced anesthesiologist at the  
12 University of Minnesota; is that correct?

13 A. To my understanding, yes, he is an attending level  
14 anesthesiologist at the University of Minnesota Hospital.

15 Q. He took no issue to the design of the simulations,  
16 in any respect; correct?

17 A. None that I was aware of.

18 Q. And you similarly witnessed the simulations and you  
19 took no issue with respect to the design as it was presented  
20 in this paper?

21 A. None whatsoever. I helped design the study and  
22 I believe this to be appropriate.

23 Q. This study, like the bubble-count study performed  
24 in the UK, was conducted in a laminar flow operating room;  
25 correct?

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2 A. It was.

3 Q. And like the laminar flow operating room in the  
4 McGovern study, this laminar flow exceeded basic  
5 requirements; correct?

6 A. As far as I understand, yes.

7 Q. The experimental design is replicable?

8 A. I believe it was, given the information that we  
9 provided in the paper.

10 Q. And an anesthesiologist stood motionless at the  
11 head of the table?

12 A. As far as I remember, yes.

13 Q. In terms of drape height, that was measured by  
14 clipping the drape to an IV pole; and for the high drape it  
15 was measured at 0.75 meters above the OR table, and the  
16 lower drape was measured at 25 meters above the OR table;  
17 correct?

18 A. Yes.

19 Q. The mannequin, which was placed on the table for  
20 the purposes of the simulation, was draped according to the  
21 protocol used by this particular hospital; correct?

22 A. Yes, it was -- it was draped -- well, by the  
23 protocol that I would use. I don't remember if I consulted  
24 Dr. Belani about the way that draping would be done, if  
25 indeed, it was any different. Generally, draping for such

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2 operations is similar, as far as I know, but I don't  
3 remember if this was one which had been written or  
4 designated as an approved method for this hospital.

5 Q. Okay. Just so we're clear, on the bottom of  
6 internal page 407 in the left-hand column, do you see the  
7 title that says, "Total Knee Replacement Experimental  
8 Setup"?

9 A. Yes.

10 Q. It says:

11 "A mannequin was laid in the supine position and  
12 draped in accordance with the standard draping protocol  
13 used by the hospital for knee replacement procedures."

14 A. In that case, that was what was done.

15 Q. And this hospital is a hospital at the University  
16 of Minnesota?

17 A. Yes, that's correct.

18 Q. The lighting arrangement was also according to  
19 standard protocol?

20 A. Yes.

21 Q. And the blanket from the Bair Hugger was affixed  
22 according to the manufacturer's instructions; correct?

23 A. It was.

24 Q. And this bubble diffuser was the same bubble  
25 diffuser used in the bubble-count experiment for the

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2 governmental study; correct?

3 A. Yes.

4 Q. So it too was designed and validated for  
5 visualization of air currents; correct?

6 A. Correct.

7 Q. Although a picture in the study shows the  
8 anesthesiologist holding the bubble wand, if you can call it  
9 that, when the study was actually performed, the wand was  
10 laid down on the OR table; correct?

11 A. That's correct.

12 Q. So the only time in which it was actually picked up  
13 was just for purposes of the photograph in Figure 6,  
14 displaying the anesthesiologist holding it?

15 A. Yes, that was not the position that was taken for  
16 data which was analyzed as -- well, statistically analyzed  
17 for this paper.

18 Q. And the position of the Bair Hugger device within  
19 the operating room was marked on the floor of the operating  
20 room?

21 A. Could you refer to the place that that's written,  
22 please?

23 Q. Yeah, it's not actually in the study, but ...

24 (Exhibit 25 marked for identification)

25 A. Thanking you.

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2 Q. Does this document bear a title "Anesthesia &  
3 Analgesia. Patient Warming Excess Heat"?

4 A. Yes.

5 Q. Does this appear to be a document in which it  
6 catalogs the reviewers' comments and the authors' response  
7 to the reviewer comments?

8 A. It does.

9 Q. If I could draw your attention to the page bearing  
10 the Bates label in the bottom right-hand corner,  
11 Belani\_000013.

12 A. Yeah.

13 Q. The middle of the page, it says:

14 "Yes, the position of all devices was marked with  
15 tape on the floor to ensure repeatable placement of the  
16 experimental equipment."

17 A. Yes. So, in between experimental runs, all  
18 equipment was placed in the same position as it had been for  
19 other runs, and those pieces of equipment, such as IV drip  
20 stands to hold the anesthesia screen, the Bair Hugger, all  
21 the movable equipment, was marked with some tape to ensure  
22 that no alteration occurred between different experimental  
23 runs.

24 Q. You have no doubts about the adequacy of the  
25 experimental setup in terms of replicating an orthopedic

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2 surgery, do you?

3 A. No, I believe that the experiment is repeatable in  
4 different environments.

5 Q. Let's look at the actual results of the experiment  
6 as depicted in Figure 3, which is on internal page 408.  
7 There are three headers, one bearing the name "Control", the  
8 other "Conductive Fabric" and the other "Forced Air";  
9 correct?

10 A. Yes.

11 Q. And in each row there are data points which have  
12 been -- is "jigged" the right word? -- in order to prevent  
13 overlap of those points?

14 A. Jittered.

15 Q. Jittered. Yeah, there we go. In figure 3, the  
16 text says "jittered". With respect to -- in this graph it  
17 shows bubble counts; yes?

18 A. Yes.

19 Q. With respect to the section on forced-air warming,  
20 the data shows that in all-but-one run, FAW, or forced-air  
21 warming, generated at least two 250 bubbles; correct?

22 A. More than that. These are root values, so root 2  
23 to root 50 bubbles. So -- well, it is an adjustment to get  
24 the data on the graph in a readable format.

25 Q. Okay.



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2 A. But it shows that -- yeah, if the forced air is  
3 between root 2 to root 50, or just under root 50 bubbles. I  
4 don't know what the absolute values are. Perhaps they're  
5 here.

6 Q. Yeah, I was looking for that as well, and I don't  
7 see them. But in any case, if we look at Figure 4, which is  
8 the root of the sum of bubble counts at the surgical site;  
9 do you see that?

10 A. Figure 4.

11 Q. On the next page, the predicted mean sum of bubble  
12 counts for forced-air warming at both drape heights, i.e.  
13 half and full drape, was well over the root of 120; correct?

14 A. Yes.

15 Q. Okay. And now, speaking of conductive fabric  
16 warming, I apologize for sending you back to Figure 3 on the  
17 prior page, but the data shows that only two runs of  
18 conductive fabric warming resulted in a bubble over the  
19 surgical site, whereas all other runs had zero bubbles;  
20 correct?

21 A. That is what this appears to show, yes.

22 Q. And with respect to the sum depicted in Figure 4  
23 for conductive fabric warming at both drape heights, the  
24 root sum appears to be 0.5?

25 A. I can't say what the actual number is, because the

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2 graph is a root graph, and there are arrow bars, but it is  
3 low.

4 Q. Okay.

5 A. Or lower than forced air. I can't give you the  
6 absolute number.

7 Q. If I can draw your attention to the prior page,  
8 directly under Table 1 is a paragraph; do you see that?

9 A. Yes.

10 Q. And in the penultimate sentence it says:

11 "Such a count represents a significant  
12 increase in the number of bubbles reaching the surgical  
13 site versus" --

14 A. Sorry, I'm lost again. Hang on. Under table?

15 Q. Directly under Table 1, not Figure 1.

16 A. Oh, where are we? Okay, yeah. Right. Under Table  
17 1, yeah.

18 Q. And just above the last sentence, it says:

19 "Predicted mean sum of bubble counts equal to  
20 0.48 ..."

21 A. Yes, yes. 0.01 respectively, yes.

22 Q. So in Figure 4, it is approximately 0.5 in terms of  
23 the bubble counts for conductive fabric warming with respect  
24 to both drape heights; correct?

25 A. That's what this appears to say.

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2 Q. Okay. And based on that same textural paragraph we  
3 were just looking at -- actually, let's go to Table 1.

4 A. Okay.

5 Q. We see:

6 "Poisson Bubble Count Model Parameters and Their  
7 Significance."

8 And the second model parameter is "patient warming  
9 device" and it has a p value of less than 0.001?

10 A. Yes.

11 Q. Does that indicate that there was a statistically  
12 significant difference between the number of bubbles at the  
13 surgical site between different types of warming devices?

14 A. That's what this would indicate, as far as  
15 I understand it, yes.

16 Q. And the warming devices here were the Bair Hugger  
17 versus the Hotdog; correct?

18 A. And versus no warming device, yeah.

19 Q. Okay. And in contrast to the McGovern study, this  
20 study found that at full drape height, there was  
21 a statistically significant difference?

22 MR. C. GORDON: Object to the form of the  
23 question.

24 A. I believe it did. I --

25 BY MR. SACCHET:

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2 Q. If you go to the paragraph of text under Table 1  
3 again.

4 A. Yes, yeah. I've got warming and control  
5 conditions, yes. So, yeah with this model, this says that:

6 "The use of forced air warming was found to result  
7 in a predicted mean sum of bubble counts equal to 132.5  
8 [which] represents a significant increase in the number  
9 of bubbles reaching the surgical site ..." for the  
10 condition of forced-air warming when compared with both  
11 conductive fabric warming and the controlled conditions  
12 where there was no warming device used. Yes.

13 Q. And the paragraph also says the factor of drape  
14 height was insignificant.

15 A. The factor of drape height was ... were not  
16 significant, yes. Were insignificant, yes.

17 Q. And we have established before, when we looked at  
18 this study, that there was a statement to the effect of  
19 bubbles having similar airborne characteristics as neutrally  
20 buoyant detergent bubbles?

21 A. That's what we were discussing earlier.

22 Q. So, based on that statement, this study would tend  
23 to show that, as a result of forced-air warming, there would  
24 be an increase in bubbles at the surgical site; correct?

25 A. This would show that in experimental conditions

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2 such as this, the used of forced-air warming in a simulated  
3 operation designed to replicate, as closely as practicable,  
4 an operative procedure. In that situation, forced-air  
5 warming had a significant -- resulted in a significantly  
6 increased transfer of air, and therefore bubbles, to the  
7 operative field compared with conductive fabric warming and  
8 no warming.

9 Q. And those results give support to the fact that the  
10 Bair Hugger could cause increased bacteria at the surgical  
11 site in comparison to conductive fabric warming?

12 A. They give support to the concept, to the theory,  
13 that the Bair Hugger may encourage air to flow from  
14 non-sterile areas, i.e. the area around the patient's head,  
15 to a sterile area, i.e. the operative field in these  
16 conditions.

17 Q. Thank you. And the results of this study are  
18 actually rather conservative in nature, given the  
19 experimental set-up; correct?

20 MR. C. GORDON: Object to the form of the  
21 question.

22 A. Can you clarify what you mean by that, please?

23 BY MR. SACCHET:

24 Q. So, some potential obstructions in the operating  
25 room were not present during this study that would have

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2 otherwise potentially interacted with the use of  
3 a forced-air warming device to create additional convection  
4 problems?

5 A. I don't think it's possible to speculate on that,  
6 because any additional devices could, when put in one  
7 position, reduce the likelihood of air -- contaminated air  
8 reaching the surgical site, or it could increase it. But  
9 it's not possible to say with certainty what a unknown  
10 condition, such as the one you state, what influence that  
11 would have.

12 Q. The lights were turned off during much of the  
13 simulation; correct?

14 A. I believe so. I can't remember; I'd need to check.  
15 I think they were positioned, certainly as for ... yeah,  
16 surgical lighting was provided by some overhead lights which  
17 were turned off during experiments. That's correct.

18 Q. And you stated earlier today that lighting can  
19 disrupted laminar airflow?

20 A. Yeah, other experiments that I've done -- I'm  
21 working on a publication at the moment which, in my opinion,  
22 indicates that operating lights have a marked effect on  
23 laminar flow.

24 Q. There was no surgical team present during the  
25 simulation; correct?

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2 A. That is correct.

3 Q. And there were no instrument trays?

4 A. That is correct.

5 (Reporter clarification.)

6 Q. Given the absence of those variables, the results  
7 are probably applicable to a variety of procedures. That's  
8 what you said a few minutes ago; correct?

9 A. They may be applicable to a variety of procedures,  
10 yes.

11 Q. And this study was published after the peer-review  
12 process; correct?

13 A. It was. It was peer-reviewed before publication,  
14 yes.

15 Q. And the editor of the section on patient safety,  
16 Dr. Sorin Brull, informed members of your team that this  
17 paper would be subject to rigorous review?

18 A. You'll have to show me where that is stated, if you  
19 could.

20 (Exhibit 26 marked for identification)

21 A. Thank you.

22 Q. In this document, dated October 25, 2011, Mark  
23 Albrecht sent you and other co-authors a forwarded letter  
24 from the Anesthesia & Analgesia editorial office; correct?

25 A. Yes, that's right.

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2 Q. And the particular editor, as denoted on the second  
3 page at the top, is "Sorin J. Brull, MD, Section Editor,  
4 Patient Safety, Anesthesia & Analgesia"; correct?

5 A. Yes.

6 Q. And she copied in the editor in chief of the  
7 journal, Steven Schafer; correct?

8 A. Yes.

9 Q. And in the text of this letter, Dr. Brull, in the  
10 second paragraph, says:

11 "Before I can make a decision about  
12 acceptance, I wanted to underscore the need for  
13 complete responses to the reviewers' comments. This is  
14 an interesting and potentially controversial study, and  
15 one that may place into question current practice. For  
16 this reason, I think we have a duty to ensure that the  
17 methodology is beyond reproach."

18 A. Yes, that is stated there.

19 Q. And I'll show you the document, I don't have to ...  
20 oh yes. If you could turn back to exhibit 25. I apologize,  
21 Mr. McGovern; I'll have to mark a different document.

22 (Exhibit 27 marked for identification)

23 A. Thank you.

24 Q. Okay. This e-mail, from Mr. Albrecht to you and  
25 other co-authors, is entitled "A&A Decision"; correct?



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2 A. Yes.

3 Q. And it is dated January 11, 2012?

4 A. Yes.

5 Q. And that came after the letter that we just looked  
6 at from Dr. Brull, correct, which is dated October 25, 2011?

7 A. Yes.

8 Q. And in this message Dr. Brull writes again to  
9 Mr. Albrecht; correct? As shown on the --

10 A. Yeah. That's right, yeah.

11 Q. And in the text of the letter, she states:

12 "First of all, I want to join the reviewers  
13 in thanking you for the significant changes you made to  
14 this manuscript. It deals with a very important topic,  
15 and this study could potentially change surgical and  
16 anesthetic practice. For this reason, we must ensure  
17 that the data are presented correctly, that the study  
18 supports the conclusions, and that the recommendations  
19 are based on irrefutable data."

20 Do you see that?

21 A. I do.

22 Q. This study was ultimately published in the same  
23 journal that Dr. Brull worked for?

24 A. Yes, that's correct.

25 Q. You would agree that the data presented in the

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2 study was irrefutable?

3 MR. C. GORDON: Object to the form of the  
4 question.

5 A. I would tend not to use the word "irrefutable", but  
6 I think the data is -- I think the study is a good study.

7 BY MR. SACCHET:

8 Q. Dr. Brull said that the recommendations in the  
9 study must be based on irrefutable data?

10 A. That's what Dr. Brull said, yes.

11 Q. And she ultimately decided, along with potentially  
12 other co-editors or reviewers of the journal, to publish the  
13 study?

14 A. Yes.

15 Q. So, in her view, it is fair to say that it was  
16 based on irrefutable data?

17 A. That's what she said, and it is very nice of her to  
18 say so.

19 Q. You continue to stand by the conclusions in the  
20 Belani paper?

21 A. I do.

22 Q. And you have no conflict of interest other than  
23 whatever was recorded in the study, which I believe shows  
24 none with respect to -- (overspeaking) --

25 A. No, well I was funded to travel to Minnesota to

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2 conduct the study, but I didn't receive any remuneration  
3 myself. My expenses were paid for this study, but -- most  
4 of them, not all, but I didn't receive payment for my  
5 involvement in this study.

6 MR. SACCHET: Let's take a break.

7 THE VIDEOGRAPHER: Shall I change the tape now,  
8 or -- we've got 20 minutes.

9 MR. SACCHET: Why don't you leave it in?

10 THE VIDEOGRAPHER: Going all off the record at  
11 eleven minutes past four.

12 (4:12 p.m.)

13 (Break taken.)

14 (4:18 p.m.)

15 THE VIDEOGRAPHER: Back on the record at eighteen  
16 minutes past four.

17 MR. SACCHET: Mr. McGovern, at this point in time  
18 I pass you, as the witness, to Mr. Gordon for him to finish  
19 the remaining part of his examination if he so wishes, and  
20 I reserve the rest of my time to respond if necessary.

21 MR. C. GORDON: I'm sorry, we should have done  
22 that in the break.

23 THE VIDEOGRAPHER: Going off the record at  
24 nineteen minutes past four.

25 (4:19. p.m.)

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2 (Break taken.)

3 (4:20 p.m.)

4 THE VIDEOGRAPHER: Back on the record at twenty  
5 past four. This is the end of DVD 3 in volume 1 of the  
6 deposition of Dr. Paul McGovern, going off the record at  
7 twenty past four.

8 (4:20 p.m.)

9 (Break taken.)

10 (4:34 p.m.)

11 THE VIDEOGRAPHER: This is the beginning of DVD 4  
12 in volume 2 of the deposition of Dr. Paul McGovern. We're  
13 back on the record at 2:34. Andrew Head has left the  
14 deposition and been replaced by Bryan Shacklady.

15 THE WITNESS: It's 4:34.

16 THE VIDEOGRAPHER: Did I say 4:34?

17 THE WITNESS: You said 2:34.

18 THE VIDEOGRAPHER: It's 4:34. Thank you very much  
19 for the correction. Thank you.

20 MR. C. GORDON: It's 2:34 somewhere.

21 EXAMINATION BY MR. C. GORDON:

22 BY MR. C. GORDON:

23 Q. Dr. McGovern, I hopefully have a few questions to  
24 follow up from some of the things you were asked. Earlier  
25 today you were asked regarding the collection of the

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2 infection data that went into the 2011 paper.

3 A. Yes.

4 Q. And I believe you were asked if Mr. Reed had  
5 collected as much data as possible, and you had said -- you  
6 had affirmed that that was your understanding.

7 A. Yes.

8 Q. Okay? And you agreed with the statement that no  
9 attempt to -- there was no attempt to artificially limit the  
10 data?

11 A. None that I know of.

12 Q. Okay. Could you take a look at exhibit 16, please.

13 A. Yes.

14 Q. The first date on exhibit 16 appears to be from  
15 October 2007; is that right?

16 A. Yes.

17 Q. And the actual study period of what you reported  
18 started in July 2008; right?

19 A. Yes.

20 Q. So in fact there were nine months of data that you  
21 all had, prior to when you decided to start the study  
22 period; right?

23 A. I don't know if that's the case.

24 MR. SACCHET: Objection to foundation.

25 (Reporter clarification.)

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2 BY MR. C. GORDON:

3 Q. Let me show you what's been marked as exhibit 28.

4 (Exhibit 28 marked for identification)

5 MR. SACCHET: Just for the record, I'm going to  
6 have a standing objection of assumes facts not in evidence  
7 with respect to this document.

8 BY MR. C. GORDON:

9 Q. This is a printout of a long spreadsheet, so  
10 there -- sort of track the numbers; you have to follow them  
11 all the way through. But the very first one on your  
12 exhibit 16 was a 72-year old hip on October 30, 2007. And  
13 if you turn ahead to page marked at the bottom  
14 Augustine\_0005198 --

15 A. Yes.

16 Q. Are you already ahead of me?

17 A. 5198, yes.

18 Q. And the 30 October 2007, there were several  
19 procedures performed, but I think, if we look over at the  
20 procedure listed as 145, that would -- does that correspond  
21 to the one you've got there?

22 MR. SACCHET: Object to form.

23 A. It is not possible to say with certainty, because  
24 there aren't enough data points to identify an individual  
25 patient. However, the data in row 145 of exhibit 28

1 DR. PAUL MCGOVERN

2 appears, as far as I can tell, to match the data in row 1 of  
3 exhibit whatever it is -- 16.

4 BY MR. C. GORDON:

5 Q. And just to further illustrate that, if you'd look  
6 ahead to 5202. Again, this is a long spreadsheet that has  
7 been printed on several different pages, but if you track  
8 the number 145, that reflects a -- an infection of  
9 enterococcus on -- well, I guess there's a date on  
10 exhibit 28, but not on -- maybe there is, on yours. But for  
11 that same October 30, 72-year-old hip, the infection is  
12 enterococcus; right?

13 MR. SACCHET: Object to form.

14 A. I mean the cells -- the data cells on both  
15 spreadsheets that you mentioned, both say "enterococcus" on  
16 them.

17 BY MR. C. GORDON:

18 Q. And your exhibit 16 just is a compilation of the  
19 procedures where there was a deep joint infection that met  
20 your criteria for inclusion in the study; right?

21 MR. SACCHET: Object to form: foundation.

22 A. It appears to be so. It's not labeled as such, so  
23 I can't absolutely confirm it, but that's what it appears to  
24 be.

25 BY MR. C. GORDON:

1 DR. PAUL MCGOVERN

2 Q. But all of the ones on exhibit 16 have infections;  
3 right?

4 A. That appears to be the case, yeah. They all  
5 mention some sort of infection, as far as I can tell.

6 Q. And I'm going to, just in the interests of speeding  
7 through this, I'm going to show you exhibit 29.

8 (Exhibit 29 marked for identification)

9 I will represent to you that exhibit 29, as  
10 difficult as it is to read, is a printout of the same  
11 spreadsheet data that we just looked at in exhibit 28,  
12 limited to WG only, as the site of Wansbeck General.

13 A. Right.

14 (Reporter clarification.)

15 MR. SACCHET: For the record, I note a standing  
16 objection to this exhibit.

17 MR. C. GORDON: You have it, counsel --

18 MR. SACCHET: Assumes facts not in evidence, and  
19 an incomplete hypothetical.

20 MR. C. GORDON: Yep, you got it.

21 MR. SACCHET: Thank you.

22 BY MR. C. GORDON:

23 Q. A little easier on the front page there, you can  
24 see 145, and you can track it all the way across to  
25 "enterococcus" on the far right.



1 DR. PAUL MCGOVERN

2 A. Where are we? Okay, 145, yes.

3 Q. Just to further verify it, let's take a look at the  
4 15 January 2008, which would be, I think, the third page?

5 A. Of?

6 Q. Of exhibit 29.

7 A. Okay. Page 3, which line?

8 Q. It looks like it corresponds to 476.

9 A. Right.

10 Q. And just as on your exhibit 16, that's  
11 a 69-year-old hip?

12 A. Yeah.

13 Q. And the exhibit 29 printout describes that  
14 condition as "staph aureus"?

15 A. Yes.

16 Q. And as does your exhibit 16. I don't want to take  
17 up a lot more time going through here. We can go back to  
18 your exhibit 16.

19 A. Right.

20 Q. And we'll focus on that, but to the extent, you  
21 know, there are questions about the full dataset ...

22 A. Right.

23 Q. ... I wanted to put exhibits 28 and 29 in front of  
24 you.

25 A. Okay.

1 DR. PAUL MCGOVERN

2 Q. So for exhibit 16, from October 2007 to June,  
3 through June, that would be a total of nine months, right?  
4 October 2007 through June 2008?

5 A. Eight. Yeah, it all depends if you're counting  
6 October.

7 Q. Counting October and June.

8 A. Inclusive? Then that covers a period including  
9 nine different months, yes.

10 Q. And just if you look at exhibit 28, you can see  
11 that the very first procedure starts on October 1.

12 A. Right, okay. Yes, yes.

13 Q. So, on your exhibit 16, in those nine months, how  
14 many infections were there?

15 A. Between October 2007 and when? August 2008?

16 Q. July of 2008. Prior to --

17 A. Six. Six.

18 Q. And -- I'm sorry, not including July. The study  
19 started July; or you used, as a study period, starting  
20 July 1; right?

21 A. Right.

22 Q. So --

23 A. I don't remember. I'd need to check the --

24 Q. And that's exhibit 13?

25 A. Right.

1 DR. PAUL MCGOVERN

2 Q. I want you to take a look, because I want to make  
3 sure we're on the same page on this. Literally. And  
4 I think it is on internal page 1540, under "Joint infection  
5 data".

6 A. What exhibit are we on again?

7 Q. I think it is 13.

8 A. All right, hang on. Okay, here we are. Yes. What  
9 page internally?

10 Q. 1540.

11 A. 1540. Yes, okay.

12 Q. So it's the -- under "Joint infection data", it's  
13 the -- you looked at the 2.5-year period starting 1 July,  
14 2008; right?

15 A. Yes. It doesn't specify 1 July. It says July  
16 2008.

17 Q. The copy I'm looking at, it doesn't say "starting 1  
18 July 2008?" Which I think is the way you folks say July 1?

19 A. I think we're lost in translation.

20 Q. I'm going to just show you what I'm looking at.

21 A. Okay. Yes, you're right.

22 Q. Okay.

23 A. Agreed.

24 Q. So, starting July 1, 2008, you looked at 2.5 years  
25 or 30 months' worth of data; right?

1 DR. PAUL MCGOVERN

2 A. Right.

3 MR. SACCHET: Object to form.

4 BY MR. C. GORDON:

5 Q. Why did you not include the nine months of data you  
6 had from October 2007 to June of 2008?

7 MR. SACCHET: Objection: foundation.

8 A. I do not know.

9 BY MR. C. GORDON:

10 Q. Do you know who made the decision?

11 MR. SACCHET: Objection: foundation.

12 A. I do not know.

13 BY MR. C. GORDON:

14 Q. Okay. So in that nine-month period that you didn't  
15 include, there were five infections in nine months; right?

16 A. It appears that's the case.

17 Q. Okay. Let just randomly start with July 1, and  
18 count nine months. It would be July, August, September,  
19 October, November, December, January, February, March.  
20 Right?

21 A. Yes.

22 Q. Okay. Can you tell me how many infections you  
23 recorded from July 1 of 2008 to March -- well, through March  
24 of 2009?

25 MR. SACCHET: Objection: foundation.

1 DR. PAUL MCGOVERN

2 A. July 2008 through to March 2009. 1, 2, 3, 4, 5, 6,  
3 7, 8, 9, 10, 11, 12, through to end of March 2009.

4 BY MR. C. GORDON:

5 Q. Okay. So the first nine months of the full dataset  
6 that you had, there are only five infections?

7 A. Yes.

8 Q. But the first nine months of the period that you --  
9 where you chose to start it, there were 12 infections in  
10 a nine-month period; right?

11 A. That is what this data shows.

12 Q. Okay. There's quite a difference between 5 and 12,  
13 isn't there?

14 MR. SACCHET: Objection to form.

15 A. There is a difference between 5 and 12.

16 BY MR. C. GORDON:

17 Q. Okay. And I'm not going to take the time now to  
18 have you actually go through and count the number of  
19 procedures, because I understand that the number of  
20 procedures can vary, month to month. But I want to do one  
21 more exercise with this exhibit 16. And looking at  
22 exhibit 13, the period in which rivaroxaban was used.

23 A. That's 13. Okay.

24 Q. That was beginning of August 2009 through the end  
25 of February 2010; correct?

1 DR. PAUL MCGOVERN

2 A. Beginning of August 2009 to -- you will have to  
3 take me back to the document because I don't remember.

4 Q. I think the rivaroxaban part is -- yes, it's in  
5 that same joint infection data section, towards the bottom.  
6 The thromboprophylaxis regimen, from July 2008 to the end of  
7 July 2009, was tinzaparin.

8 A. Right.

9 Q. And so where is the rivaroxaban? Oh, I'm sorry.  
10 There it is: the next line. From August 2009 to  
11 February 2010, Rivaroxaban was provided.

12 A. Right.

13 Q. Okay. And actually, if you look at exhibit 21.

14 A. Yes.

15 Q. On the first page there, it says "between  
16 February 2009 and February 2010."

17 A. Yes.

18 Q. So if -- go back to your exhibit 16. If you look  
19 at that period of August through February -- August 2009  
20 through February 2010, that's August, September, October,  
21 November, December, January, February.

22 A. Yes.

23 Q. Seven months.

24 A. Yeah.

25 Q. And if you look at exhibit 21, Dr. Reed also talks

1 DR. PAUL MCGOVERN

2 about it being a seven-month period. Could you please count  
3 up the total number of infections that you, your dataset,  
4 had for that seven-month period.

5 A. From August to?

6 Q. February. To the end of February.

7 A. To the end of February.

8 MS. ZIMMERMAN: Do you have a copy of that? We  
9 can't find it in the binder.

10 MR. C. GORDON: Which one?

11 MS. ZIMMERMAN: The chart, the spreadsheet you're  
12 referring to. I don't know if it's in one of these binders.

13 MR. C. GORDON: 16? You marked it.

14 MS. ZIMMERMAN: Our 16 is what you're using?

15 MR. C. GORDON: Yeah.

16 A. From the beginning of August 2009 to the end of  
17 February 2010: 18.

18 BY MR. C. GORDON:

19 Q. Now if you'd look at exhibit 21, that was the  
20 Jensen et al study, including Dr. Reed?

21 A. Yeah.

22 Q. How many infections did they report for that, the  
23 same seven-month period?

24 MR. SACCHET: Objection to form: foundation.

25 A. How many infections did you ...

1 DR. PAUL MCGOVERN

2 BY MR. C. GORDON:

3 Q. Again, this is exhibit 21. We'll look at page 523.

4 A. Right.

5 Q. I guess it's internal 93.

6 A. Yes.

7 Q. And there, group 1 is previously defined as the six  
8 months prior to the switch to rivaroxaban.

9 A. Right.

10 Q. And group 2 is the seven-month rivaroxaban?

11 A. Right.

12 Q. And under "Results", the third paragraph down.

13 A. Yes.

14 Q. There are 14 infections reported; right?

15 MR. SACCHET: Object to the form.

16 A. That shows that microbiology was cultured in 14  
17 locations.

18 Q. And the comparator that was used in this study, and  
19 exhibit 21, to determine whether rivaroxaban did or did not  
20 have a statistically significant impact on joint infection  
21 rates, that's the number. It was 14 versus 5 in group 1;  
22 right?

23 MR. SACCHET: Objection to form.

24 A. I'm not following you.

25 BY MR. C. GORDON:



1 DR. PAUL MCGOVERN

2 Q. Again, look at page 523, and it says:

3 "Of those patients who returned to theatre,  
4 microbiology results showed that five of the nine (55%)  
5 in group 1 had a deep infection compared with 14 of 22,  
6 (63.6) in group 2."

7 A. Right, yeah.

8 Q. "The overall deep infection rate in group 1 was 1%  
9 (95% CI 0.4 to 2.4), compared with 2.5% (95% CI 1.5 to 4.2)  
10 in group 2 (with a P value of 0.102)."

11 A. Right.

12 Q. So the comparator in this study was 1 percent based  
13 on 5, versus 2.5 percent based on 14; right?

14 A. That's microbiology confirmed deep joint infection.  
15 That's not the only way of measuring deep joint infection.

16 MR. SACCHET: Objection to form.

17 (Reporter clarification.)

18 BY MR. C. GORDON:

19 Q. Thank you. I'm not trying to cast aspersions on  
20 the authors of exhibit 21. There is that difference. There  
21 was also -- I want to, just in fairness, point out the  
22 criteria for deep joint infections in exhibit 21. And that  
23 paper was infections presenting within 30 days.

24 MR. SACCHET: Objection: move to strike a  
25 preamble, no question pending, testimony from counsel.

1 DR. PAUL MCGOVERN

2 BY MR. C. GORDON:

3 Q. Was the 30-day -- was that the same cut-off period  
4 that you used?

5 A. I cannot remember.

6 MR. SACCHET: Objection to the foundation.

7 BY MR. C. GORDON:

8 Q. Let's take a look at your exhibit 13 and see what  
9 your definition was, or your cut-off period. Again, it is  
10 all in that -- everything seems to be in that one paragraph  
11 showing infection data.

12 A. Which page are we on in exhibit 13?

13 Q. It is internal page 1540.

14 A. Yes. Yes, so: "Infection was diagnosed by surgical  
15 site infection nurses according to english Health Protection  
16 Agency criteria for deep infection ... Only infections  
17 presenting within 60 days of surgery were included.

18 Q. So your period of surveillance was a little longer  
19 than exhibit 21, and in exhibit 21 they were using  
20 microbiology as the --

21 A. Different methods were used in different studies to  
22 define when a patient had infection.

23 Q. Okay. So for the -- for that rivaroxaban period  
24 using your criteria, there were, in fact, 18 infections?

25 MR. SACCHET: Objection --

1 DR. PAUL MCGOVERN

2 BY MR. C. GORDON:

3 Q. -- in that seven-month period; right?

4 A. Which data are you using?

5 Q. Exhibit 16.

6 A. On exhibit 16, we're saying that between 1 August  
7 and the end of February 2009, I think --

8 Q. 2010.

9 A. 2010, correct. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11,  
10 12, 13, 14, 15, 16, 17, 18 infections, yes.

11 Q. Okay. And in the exhibit 21, where they ended up  
12 comparing that 1 percent to the 2.5 percent, the period  
13 of -- what they defined as group 1, the pre-rivaroxaban time  
14 period, that began in February 2009 for six months; right?

15 MR. SACCHET: Objection to form: foundation.

16 BY MR. C. GORDON:

17 Q. February, March, April, May, June -- I'm sorry,  
18 five months. February, March, April, May, June.

19 A. Sorry, what began it? This is the --

20 Q. No, my math is off. Don't rely on me. Look on the  
21 front page of exhibit 21.

22 A. The front page of --

23 Q. Page 91.

24 A. -- of exhibit 21 --

25 Q. Under "Patients and Methods".

1 DR. PAUL MCGOVERN

2 A. Yeah.

3 Q. What was the period that would -- that was group 1?

4 A. 1 February 2009 and 31st July 2009 was group 1.

5 Q. Okay, and that is six months. Now let's look at  
6 your exhibit 16 and count the number of infections that  
7 report for the period of February 1, 2009, through  
8 31st July 2009.

9 A. February 1, 2009 ...

10 MR. SACCHET: I don't see that on the --

11 A. To when?

12 BY MR. C. GORDON:

13 Q. 31 July, 2009.

14 A. Three.

15 Q. Okay. So, for that six-month period that the study  
16 exhibit 21 refers to is a group 1, when they were still on  
17 tinzaparin, your data show three infections; right?

18 MR. SACCHET: Objection to form.

19 A. Between 1 February 2009 and 31st July 2009, the  
20 data from the study shown in the exhibit 16 showed three  
21 infections.

22 BY MR. C. GORDON:

23 Q. And in the study in exhibit 21, they reflect five  
24 microbiology confirmed infections in that time frame; is  
25 that right?

1 DR. PAUL MCGOVERN

2 MR. SACCHET: Objection: foundation.

3 BY MR. C. GORDON:

4 Q. Internal page 93 are the results.

5 A. 93. Yes.

6 Q. Okay.

7 A. Well, yeah, five have a microbiology confirmed  
8 infection.

9 Q. I understand how the different methods result in --  
10 resulted in undercounting in exhibit 21, but how -- do you  
11 have any understanding as to how they would have gotten five  
12 when you only got three?

13 MR. SACCHET: Objection to the preamble, and move  
14 to strike the comments that they were undercounting; made by  
15 counsel as opposed to the witness.

16 A. Could you repeat the question, please.

17 BY MR. C. GORDON:

18 Q. Do you have any understanding as to why, in the  
19 study in exhibit 21, they recorded five infections in the  
20 pre-rivaroxaban period, when your data show only three in  
21 that same period?

22 MR. SACCHET: Objection: form. Objection:  
23 foundation.

24 A. The criteria used for deciding what is and is not  
25 an infection is not black and white. I don't know what

1 DR. PAUL MCGOVERN

2 happened with -- really, with the methods used -- sorry, the  
3 criteria are different, and the decision of whether an  
4 infection exists or not can be made through several  
5 different methods. It is stated in both papers that  
6 different methods were used to decide if patients had an  
7 infection or not, and it seems likely to me that the  
8 discrepancy in the reported rate of infection in the date  
9 ranges concerned can be accounted for by the fact that  
10 completely different definitions of infection and criteria  
11 for the diagnosis of infection in these papers were used for  
12 the two different studies.

13 BY MR. C. GORDON:

14 Q. Okay. So, just using your -- the criteria you  
15 used, in the six months of tinzaparin before the switch to  
16 rivaroxaban, there were only three infections; and during  
17 the rivaroxaban period of seven months, there were a total  
18 of 18 infections; right?

19 MR. SACCHET: Objection to form, foundation.

20 A. In those two ... without original data for these  
21 two, I can't say for sure that, even though they're in the  
22 same hospital, that the patients we're counting here  
23 definitely fall into this group in this paper. I can't say  
24 that they're the same thing. And so I can't draw that  
25 conclusion, because I haven't got -- the data are -- the

1 DR. PAUL MCGOVERN

2 patient cohorts may be similar, but I don't have enough  
3 evidence to draw a parallel, because the data have not been  
4 analyzed together and not been presented together.

5 BY MR. C. GORDON:

6 Q. Putting aside whatever was recorded in exhibit 21,  
7 based on your published paper --

8 A. Yes.

9 Q. -- the rivaroxaban period coincides with 18  
10 infections; right?

11 A. During --

12 MR. SACCHET: Objection to form.

13 A. During the rivaroxaban period, if it's stated that  
14 ... right, where is the rivaroxaban? Right, August 2009 to  
15 February 2010, 18. That's stated as the rivaroxaban period,  
16 and this reverted to tinzaparin from day one,  
17 postoperatively, in February. And in that period mentioned  
18 in the paper, there were 18 infections recorded for that  
19 study, yes.

20 BY MR. C. GORDON:

21 Q. Okay. Now on your exhibit 16, if you turn to the  
22 third page in, toward the bottom it looks like there are six  
23 infections listed there, and under "BC" it says  
24 "Transition". Do you see that?

25 A. Yes, yes.

1 DR. PAUL MCGOVERN

2 Q. So those would have occurred during the period when  
3 you were transitioning from Bair Hugger to Hotdog; right?

4 A. Yes.

5 Q. Is it possible that any of those transition  
6 procedures were done with a Hotdog?

7 MR. SACCHET: Objection: foundation.

8 A. I do not know.

9 BY MR. C. GORDON:

10 Q. Would that data have been available to you when you  
11 wrote the paper?

12 MR. SACCHET: Objection to form: foundation.

13 A. I do not know.

14 BY MR. C. GORDON:

15 Q. Okay. Is there any reason why you decided not to  
16 try and figure out whether those six infections were  
17 involving Hotdog patients or Bair Hugger patients?

18 MR. SACCHET: Objection: foundation,  
19 argumentative.

20 A. Could you repeat the question, please?

21 BY MR. C. GORDON:

22 Q. Well I guess I missed a step here. Did you do  
23 anything, when you were writing the paper, to try and see if  
24 the infections that arose during the transition period  
25 occurred in patients who had been warmed with the



1 DR. PAUL MCGOVERN

2 Bair Hugger or the Hotdog?

3 MR. SACCHET: Objection to form.

4 A. So you're asking if it was documented, or if it was  
5 recorded anywhere, if those patients were using Bair Huggers  
6 or -- had Bair Huggers or HotDogs used for their procedures,  
7 and if that data was available, and if that data was or  
8 could have been put in the paper? Is that what you're  
9 saying?

10 BY MR. C. GORDON

11 Q. Right.

12 A. Right. Well, I don't know what happened; I did not  
13 collate this data. But to my knowledge it's not, or wasn't,  
14 routine practice to record the technology of warming used  
15 during a procedure. That would not be standard practice,  
16 and because this was a retrospective study, it was not known  
17 at the time of the procedures that this data would be  
18 looked at.

19 Q. So whether all six of those were Bair Hugger, all  
20 six were Hotdog, or some combination thereof, you just don't  
21 know?

22 A. And that's why they're marked clearly as  
23 a transitional period, because it's not clear whether they  
24 are Hotdog or Bair Hugger procedures.

25 Q. Okay. Line 44, you indicated was a procedure that

1 DR. PAUL MCGOVERN

2 involved the Bair Hugger; is that right?

3 A. Yes.

4 MR. SACCHET: Objection to form, foundation.

5 BY MR. C. GORDON:

6 Q. And if we go back to the front page of exhibit 16,  
7 it looks like number 44 occurred on September 15, 2010; is  
8 that right?

9 A. One, two, three; one, two, three. Yes.

10 Q. Why was there a procedure using Bair Hugger in  
11 September 2010?

12 MR. SACCHET: Objection: foundation.

13 A. I don't know.

14 BY MR. C. GORDON:

15 Q. Right, and you didn't report that anywhere in your  
16 paper, did you?

17 A. Not to my knowledge.

18 Q. In fact, if you look at exhibit 13 on internal  
19 page 1343.

20 A. Exhibit 13, what page?

21 Q. 1543; I'm sorry. Bad eyes. Figure 7, which we  
22 talked about a little bit yesterday.

23 A. Right.

24 Q. At the top of Figure 7, those little circles, those  
25 are representations of when infections occurred; right?

1 DR. PAUL MCGOVERN

2 A. Right.

3 Q. Where is the infection that's on your exhibit 16,  
4 as identified as number 44, where would one find that on  
5 that Figure 7?

6 MR. SACCHET: Objection: foundation.

7 A. Sorry, repeat that, please?

8 BY MR. C. GORDON:

9 Q. Figure 7, at the top, shows circles reflecting  
10 infections along the time axis on the bottom.

11 A. Yes, yes.

12 Q. And you've indicated that number 44, a September 15  
13 2010 procedure, used a Bair Hugger and resulted in an  
14 infection. And I'm wondering where that particular one  
15 would be reflected on that timeline?

16 A. That would be reflected --

17 MR. SACCHET: Objection to form.

18 A. -- in -- well, it would be reflected in that  
19 timeline in September 2010.

20 BY MR. C. GORDON:

21 Q. Okay. Well, looking at the Figure 7, how many  
22 total infections are reflected in the conductive fabric  
23 period from July 2010 to January 2011?

24 MR. SACCHET: Objection to form.

25 A. On Figure 7?

1 DR. PAUL MCGOVERN

2 Q. Yes.

3 A. Well, I can see three, maybe four, marks. It's not  
4 clear from the copy.

5 Q. Okay. Well, you report three, right, in the text?

6 A. Right, yeah.

7 MR. SACCHET: Objection to form.

8 BY MR. C. GORDON:

9 Q. And the dates of the three on exhibit 16 would be  
10 September 1, October 18, and November 22 of 2010; right?

11 A. October -- well, September 1, September 15 and  
12 November 22, yes.

13 Q. So what I'm trying to understand is, if there are  
14 three dots in that -- in the conductive fabric box, what  
15 happened to the September 15, 2010, forced-air warming?

16 MR. SACCHET: Objection: misstates the testimony.  
17 And form.

18 A. It depends if the data was jittered. This doesn't  
19 say -- oh no, it does say the data were jittered to avoid  
20 overprinting. It is not apparent to me if the 15th and the  
21 1st September data points on this graph, due to the low  
22 resolution of the graph, are overlaid on each other, or if  
23 that data point is not there. I can't tell.

24 BY MR. C. GORDON:

25 Q. If you didn't have information available to

1 DR. PAUL MCGOVERN

2 determine which of the transition procedures involved  
3 Bair Hugger versus Hotdog, how are you able to tell that the  
4 September 15 procedure, which was after you had transitioned  
5 to Hotdog, for some reason used a Bair Hugger?

6 A. I don't know.

7 MR. SACCHET: Objection to form, foundation,  
8 assumes facts not in evidence.

9 A. I don't know how you would.

10 BY MR. C. GORDON:

11 Q. I didn't write down the exhibit number, but it's  
12 your -- it was marked as the write-up of the microbiology  
13 study earlier on.

14 A. Oh, yeah.

15 MS. ZIMMERMAN: Oh, I'm sorry. Exhibit 6 was  
16 tab 24.

17 MR. C. GORDON: Exhibit 6?

18 MR. SACCHET: It looks similar, probably. Is that  
19 the one that the --

20 MR. C. GORDON: That's your copy.

21 MR. SACCHET: Okay, yeah.

22 MR. C. GORDON: That's the only other one I need  
23 to know.

24 MR. SACCHET: The date is June 30, 2010. I don't  
25 know the text. Can I see? Okay. It's going to take me

1 DR. PAUL MCGOVERN

2 a moment to find.

3 BY MR. C. GORDON:

4 Q. If you look at exhibit 6 now, switch gears. What  
5 was this?

6 MR. SACCHET: I think that's 2.

7 MR. C. GORDON: Okay. Have you got 6?

8 A. It's here somewhere. Six.

9 Q. If you'd turn to the second page, comment PS3: "Is  
10 there any info about the sensitivity of the device, i.e." --

11 A. Exhibit 6 doesn't have --

12 MR. SACCHET: This isn't actually -- is this the  
13 comment draft one?

14 MR. C. GORDON: Yes, the comment one.

15 MR. SACCHET: That's not --

16 MR. C. GORDON: Sorry. You know what, without  
17 looking at the documents, I think I can just tee this up.

18 BY MR. C. GORDON:

19 Q. You remember being asked questions about the  
20 Handilaz capability of measuring only 0.3, 0.5, and  
21 5 microns?

22 A. Yes.

23 Q. And your colleague -- one of your colleagues had  
24 raised a question about the sensitivity of the device;  
25 right?

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2 A. Yes.

3 Q. And she had -- I believe it's she --

4 A. He.

5 Q. He. I apologize. He had asked about its relevance  
6 to the pathogens; right?

7 A. Right.

8 Q. And we, counsel for the plaintiffs, established  
9 that the Handilaz was not, as far as you know, counting  
10 particles as small as 0.2 microns?

11 A. It's not designed to record data in that range,  
12 yes.

13 Q. Okay. And I would -- with Brownian motion, it  
14 might possibly; right?

15 A. It may, yeah.

16 Q. But assuming, for the sake of argument, it doesn't  
17 pick up a 0.2 size micron, are you aware of any bacteria  
18 that causes deep joint infections that is 0.2 microns?

19 MR. SACCHET: Objection: foundation.

20 A. I don't know about the size of bacteria in relation  
21 to those which are pathogenic for deep joint infection, so  
22 I couldn't comment of the diameters of bacteria.

23 (Reporter clarification.)

24 BY MR. C. GORDON:

25 Q. In your medical training, do you have any kind of

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2 general sense as to what the range of sizes of bacteria are,  
3 as opposed to viruses or fungal spores?

4 MR. SACCHET: Objection: foundation, asked and  
5 answered.

6 A. Well, bacteria will be significantly larger, orders  
7 of magnitude larger than a virus.

8 (Reporter clarification.)

9 A. But I would need to look up exact numbers, because  
10 I wouldn't want to misspeak.

11 BY MR. C. GORDON:

12 Q. I appreciate that. Let's go on to exhibit 6.

13 A. I'm on exhibit 6.

14 Q. Okay. Second page, a variant of your e-mail, you  
15 make reference to --

16 A. E-mail? This is not an e-mail on exhibit 6.

17 Q. I apologize. I guess we're getting the numbers all  
18 screwed up.

19 MR. SACCHET: Which one is that?

20 MR. C. GORDON: It's the --

21 MR. SACCHET: I think it's exhibit 2.

22 MR. C. GORDON: "Next paper for review" is the  
23 title of it.

24 MR. SACCHET: I think it's 2.

25 BY MR. C. GORDON:



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2 Q. I apologize, then. So you can just look at mine.  
3 It is just that one line about the 800 watts.

4 A. Right, yeah.

5 Q. Where did you get the information that there's 800  
6 watts of excess heat?

7 MR. SACCHET: Objection: foundation.

8 A. I don't remember. But if the unit is powered and  
9 rated at 800 watts, then it will output that power.

10 BY MR. C. GORDON:

11 Q. Are you familiar with the difference between  
12 a maximum power rating and the actual output of an  
13 electrical appliance?

14 A. To a certain extent.

15 Q. Are they always -- are they typically the same?

16 A. No.

17 Q. Okay. If you turn to exhibit 24, I'm pretty sure  
18 I got this one right.

19 A. Yes, 24.

20 Q. On the second page, you were -- counsel for the  
21 plaintiff read the title: "Forced-air warming linked to  
22 periprosthetic total joint replacement infections." It then  
23 says "Scott D. Augustine M.D., Paul D. McGovern M.D."

24 A. It does.

25 Q. Did you write this?

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2 A. I did not.

3 Q. Have you ever seen it before?

4 A. No, not to my recollection.

5 Q. At the very beginning of today's testimony that we  
6 were -- there were some questions about peer review. The  
7 peer-review process.

8 A. Yes, yes.

9 Q. Okay. Peer reviewers can only review what they're  
10 presented; right?

11 A. Yes.

12 Q. And so, if data are omitted, or things are  
13 presented in a way that might be inaccurate or misleading,  
14 the reviewers can't figure that out, necessarily; right?

15 A. That is true.

16 MR. SACCHET: Objection to foundation. I'd also  
17 like to ask for a time count, and I object to further  
18 questioning if it is beyond 7 hours.

19 BY MR. C. GORDON:

20 Q. Have you ever heard of a Richard Eastil, M.D.,  
21 a professor of bone metabolism at the University of  
22 Sheffield?

23 A. I may have, but I don't recall.

24 Q. Have you ever heard -- recall hearing anything  
25 about a study that was published in the Journal of Bone and

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2 Mineral Research concerning the drug actonel?

3 MR. SACCHET: I'm going to object again, and ask  
4 for a time count before further questioning proceeds, in  
5 violation of Federal Rules of Civil Procedure.

6 MR. C. GORDON: Your objection is noted, counsel.

7 MR. SACCHET: Well, I'm calling for a time count.

8 THE VIDEOGRAPHER: I'm doing it. I'm doing it.  
9 Seven hours, two minutes.

10 MR. SACCHET: You're over.

11 A. Could you repeat the question, please?

12 MR. SACCHET: Again, I object to  
13 further questioning --

14 MR. C. GORDON: Your objection is noted, counsel.

15 MR. SACCHET: Now that we know the time is over,  
16 you're continuing to ask questions and it violates the  
17 Federal Rules.

18 MR. C. GORDON: No, I'm continuing to ask  
19 questions of this witness, and if your objection is  
20 sustained by the court, then all these questions, I guess,  
21 are worthless.

22 MR. SACCHET: Well, I have a continuing objection  
23 right now --

24 MR. C. GORDON: Yes you do.

25 MR. SACCHET: -- and I'm reading this into the

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2 record: the plaintiffs are adjourning this deposition  
3 until and unless defendants seek and obtain --

4 MR. C. GORDON: No. If you want to leave, go  
5 ahead. I'm going to continue asking questions.

6 MR. SACCHET: (overspeaking): leave of court  
7 enlarging the time beyond 7 hrs allowed by the federal rules  
8 of civil procedure --

9 THE COURT REPORTER: Okay, I can't take any of  
10 this down unless you --

11 MR. SACCHET: I'm going to continue if Mr. Gordon  
12 is going to continue speaking.

13 MR. C. GORDON: All right.

14 MR. SACCHET: Background here, irrelevant. Third  
15 trip to the UK for this deposition. The parties have long  
16 discussed splitting time equally. When deposition was  
17 continued due to sudden illness of Mr. Gordon, it was  
18 re-noticed to commence yesterday, January 4, 2017.

19 Dr. McGovern generously agreed to appear voluntarily and  
20 agreed to provide two full days of testimony. 3M examined  
21 the witness yesterday for 6 hrs and 17 mins and then passed  
22 the witness. The plaintiffs commenced examination this  
23 morning, having prepared three times, with detailed  
24 outlines, timed and rehearsed for 7 hours. Just after  
25 3:00 p.m. today, counsel for 3M advised he has several hours

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2 of additional questioning and planned to continue the  
3 deposition for a third day, knowing plaintiffs booked to  
4 return to the United States tomorrow.

5 MR. C. GORDON: That's a total lie, counsel.  
6 I said I had about an hour of questioning. I never said  
7 several hours. Don't lie.

8 MR. SACCHET: -- (overspeaking) -- in the  
9 interests of allowing 3M the full 7 hrs allowed by the  
10 Federal Rules of Civil Procedure, the plaintiff's expedited  
11 examination, advised of the potential need to involve the  
12 District of Minnesota if 3M needs to enlarge their  
13 examination period beyond 7 hours. Plaintiffs further  
14 passed the witness after 5 hours and 1 minute of testimony.  
15 Counsel for 3M since re-examined the witness for a total of  
16 7 hours and 3 minutes. Plaintiff's counsel advised that  
17 under rule 30D of the Federal Rules Procedure, this requires  
18 the parties seeking to extend beyond the 7-hour time period  
19 allowed to bear the burden to show good cause to get  
20 additional time. The case citation for this is the District  
21 of Minnesota Cardenas v Prudential 99-1421, issued on  
22 May 16, 2003. Another citation is Jenson v Astrazenica  
23 bearing case number 02-4844, issued on August 30, 2004.

24 3M advised only have -- 3M advised that they  
25 only had 1 hour of questioning. Plaintiffs reject the

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2 gamesmanship in these depositions would continue.

3 Attempts to deny plaintiff's ability for examination.

4 Plaintiffs are adjourning this deposition and are

5 available for call with the court if plaintiffs

6 seek -- if defendants seek an emergency relief.

7 MR. C. GORDON: This is our deposition. We're not  
8 adjourning. You're welcome to leave or stay.

9 Dr. McGovern, I'm sorry that you -- your time  
10 has been impinged on by that lengthy soliloquy.

11 MR. SACCHET: The time is being impinged by  
12 continuing examination of the witness and violation of the  
13 Federal Rules of Civil Procedure.

14 MR. C. GORDON: Do you recall hearing anything  
15 about a study about the drug actonel, an osteoporosis drug?

16 A. I do not recall such a study.

17 Q. Okay. Have you ever heard of a Doctor Andrew  
18 Wakefield?

19 A. I haven't heard of Dr. Andrew Wakefield.

20 Q. And are you familiar with the research that he  
21 published that purported to show a link between the MMR  
22 vaccine and autism?

23 A. I've not read the research itself, but I'm familiar  
24 with the media attention that that research has received.

25 (Reporter interruption.)

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2 MR. SACCHET: We're exiting the room.

3 MR. C. GORDON: Well then, I'm calling the court,  
4 and if you're gone and the judge says to continue, that's  
5 your problem.

6 THE VIDEOGRAPHER: I need to be instructed to go  
7 off the record, otherwise I keep running.

8 MR. C. GORDON: This is outrageous.

9 THE VIDEOGRAPHER: From both of you. Sir, can  
10 I go off the record?

11 MR. C. GORDON: Not yet.

12 MS. ZIMMERMAN: Yes, you can go off the record.

13 THE VIDEOGRAPHER: Both parties have to say.

14 (Parties for the Plaintiffs exit the room.)

15 MR. C. GORDON: Is the camera still running? Just  
16 leave it running. I need to get the phone number.

17 (Off-the-record discussion between Mr. Gordon  
18 and the court reporter regarding whether the  
19 transcription should continue.)

20 MR. C. GORDON: I've actually only got five  
21 minutes left of questions, and I'm done.

22 THE COURT REPORTER: The other parties didn't  
23 stipulate whether they wanted the note to continue or not.

24 MR. C. GORDON: Clearly the plaintiffs don't want  
25 it to continue, and they were afforded the opportunity to

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2 stay here, and I'm running the risk, I guess, of this being  
3 excluded.

4 MR. SHACKLADY: Do you wish to call the court?

5 MR. C. GORDON: No.

6 MR. SHACKLADY: I have no objections.

7 MR. C. GORDON: No. It doesn't matter. They're  
8 already gone.

9 (off-the-record telephone conversation.)

10 BY MR. C. GORDON:

11 Q. Earlier you were asked some questions about the 3.8  
12 and the increased risk, and you were -- your testimony is  
13 what it is, but you were precise in how you responded to  
14 that, as to what it meant for there to be an increased odds  
15 ratio, or an odds ratio of 3.8. Do you recall that line of  
16 testimony?

17 A. I do recall that line of testimony.

18 Q. Here's the question I want to ask you. You're  
19 aware of research that demonstrates that the in-hospital  
20 mortality rate for people that have CPR is pretty high,  
21 somewhere as high as 70-90 percent; right?

22 A. Yes, very high.

23 Q. So, if somebody were to do a study for some reason,  
24 and look at in-hospital mortality rate as the endpoint, and  
25 divide people into two groups, those that had CPR and those



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2 that didn't have CPR, there would probably be a really  
3 enormous odds ratio that people with CPR would die in  
4 hospital versus people who don't have CPR; right?

5 A. I think speculating on that without a precise study  
6 design, and the statistical analysis that you're referring  
7 to, means that I cannot speculate on that. I can't comment  
8 on a hypothetical situation without data in front of me and  
9 without a calculated odds ratio.

10 Q. For the purposes of this question, just assume that  
11 there is an odds ratio in excess of three for looking at  
12 a subgroup of people who had CPR versus a subgroup of people  
13 who didn't have CPR. And I'm just using this as an example  
14 to try and understand what you were saying. Were you saying  
15 that the fact that there is an increased odds ratio just  
16 means, on the basis of those data, the people in the CPR  
17 group were more likely to die in hospital than the people in  
18 the non-CPR group, but that doesn't mean that they -- their  
19 increased death rate was because they had CPR?

20 A. I find it difficult to interpret and understand  
21 exactly what you're saying, because I -- as you're speaking,  
22 I'm trying to imagine a study with two cohorts. But to know  
23 what an odds ratio is, I need to know what the endpoint of  
24 the study is. If the endpoint of the study is death, then  
25 that's one endpoint. But an endpoint of a CPR study could

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2 be hospital stay; it could be any infection. So, to answer  
3 that question, I require quite a lot more precision to  
4 understand what you're trying to delineate. I can't --  
5 forgive me -- grasp what you're trying to specify with the  
6 amount of detail you've given me.

7 Q. I'm trying to set up a hypothetical that I will  
8 concede is absurd. If somebody were -- if somebody did an  
9 audit of a hospital and said: "Okay, we want to look at all  
10 the in-hospital deaths in the parts 12 months" --

11 A. You wanted to look at all in-hospital deaths in the  
12 last 12 months, okay.

13 Q. And the only differentiating factors they looked at  
14 was whether the patient had CPR or not.

15 A. So, all in-hospital deaths within 12 months,  
16 looking at a group who had CPR and a group that didn't.

17 Q. And assume that the odds ratio is fairly high; that  
18 if you were in the CPR group, you were considerably more  
19 likely to die in hospital than if you were in a non-CPR  
20 group.

21 A. As you said, it's absurd.

22 Q. I agree. No one would do this study. But my point  
23 is, the fact that there's -- there would be an increased  
24 odds ratio, a huge odds ratio, doesn't mean that CPR is the  
25 cause of the death; right?

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2 A. At study that examines two variables and  
3 demonstrates that one condition has an increased chance of  
4 occurring when compared with another condition does not  
5 necessarily prove causality. The study in question would  
6 need to be designed and controlled for appropriately to be  
7 able to draw a causal conclusion. So, it's conceivable,  
8 within the suspension of disbelief that I'm having to go  
9 through, that the CPR study you mention could be designed to  
10 demonstrate causality. CPR -- since we're going down this  
11 path -- possibly, in some people, causes some harm; but it's  
12 a little bit far out of the realms of reality for me to be  
13 able to come up with an answer that's coherent and sensible,  
14 but to -- I can't be more specific than that.

15 Q. Fair enough. You agree that correlation, in and of  
16 itself, does not prove causality?

17 A. Absolutely. Correlation does not, in and of  
18 itself, prove causality.

19 Q. And a high odds ratio, comparing two things, does  
20 not demonstrate a -- does not prove a causal relationship?

21 A. A high odds ratio simply means that something  
22 happened -- or is likely to happen, depending on the  
23 context -- significantly more frequently, or more frequently  
24 than another condition. It does not prove causality unless  
25 the study is appropriately designed so that it -- so that

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2 the question asked, the null hypothesis, that the design of  
3 the study is set up to demonstrate, or attempt to  
4 demonstrate, causality.

5 Q. The last thing want to ask you about is there was  
6 that video clip that was on a DVD.

7 A. Yes.

8 Q. Where was that video clip from?

9 A. That was filmed in Wansbeck Hospital by myself.  
10 I think that was while the study investigators were  
11 preparing for what you've heard here as 'The McGovern Study  
12 of the 2011 Journal of Join and Bone Surgery of Britain  
13 paper.'

14 Q. Where was it posted?

15 A. To YouTube and to a blog:  
16 Northumbriaorthopedics.blog spot.com, if memory serves  
17 correctly.

18 Q. And on YouTube, there's something called orthopod  
19 research; right?

20 A. That's correct.

21 Q. Is that something you have some responsibility for?

22 A. I have created that account and I posted the videos  
23 to that account.

24 Q. And I'll call it up here, because I had it ready to  
25 go. There's a 1 minute, 58 second video on it, on orthopod

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2 research, on YouTube?

3 A. Yes.

4 Q. Called "FAW versus CWB."

5 A. Yes.

6 Q. I assume you're familiar with it, if you want to --

7 A. No, I am familiar with that video. I produced it  
8 and recorded it and narrated it.

9 Q. And narrated it.

10 A. And narrated it, yes.

11 Q. You have a very distinctive voice. And just for  
12 simplicity's sake, I took the liberty of getting some  
13 screenshots, one per second. This would be exhibit 30.

14 (Exhibit 30 marked for identification)

15 Of this YouTube video, this FAW versus --  
16 what's it called? -- CWB.

17 A. Right.

18 Q. Perhaps I'll have something in the record. Was  
19 this -- the activities that were depicted in here, was this  
20 part of what became the McGovern paper? The McGovern study?

21 A. No, this is occurring at a similar time, but none  
22 of these images are under controlled conditions. They're  
23 not timed conditions, because there's movement around the  
24 area. So this is filming while setting up and informally  
25 experimenting with the equipment to see what effects we

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2 could see with the equipment that we had.

3 Q. And the set-up here, that's not the set-up you  
4 would use for a hip or a knee --

5 A. No, it's not. It's the set-up that you would use  
6 for a -- perhaps for an upper-body operation; but rather  
7 like the microbiology paper that we were discussing earlier,  
8 this is not particularly representative of any particular  
9 operation, and it is especially not representative of a hip  
10 or knee arthroplasty surgery.

11 Q. Okay. And there's no draping over either of the  
12 heating devices; is that right?

13 A. That's correct.

14 Q. And I notice that the portion of the video that --  
15 involving the Bair Hugger, the back area seems to be  
16 darkened, whereas with the Hotdog it's -- there's no  
17 covering over the door, and it seems quite a bit lighter?

18 A. That is true. There's a drape hung up on the --  
19 I think near -- I think it might be on the doors, actually,  
20 of the operating room.

21 Q. Why the difference?

22 A. Because -- to provide visual contrast.

23 Q. On the Bair Hugger one?

24 A. It's -- well, on the Bair Hugger ones, the visual  
25 contrast is there, yes.

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2 Q. Well, why wasn't that done when you did the  
3 demonstration on the Hotdog?

4 A. Because, as I explained earlier, these images were  
5 taken while experimenting and while understanding the  
6 equipment as it was being used at the time.

7 Q. So, did you post videos from the actual experiment  
8 that you relied on for the paper itself?

9 A. I did not.

10 Q. Why?

11 A. The videos weren't used for the experiment. These  
12 were -- still-frame images were used in the experiment, as  
13 I remember.

14 Q. Why didn't you use video for the experiment?

15 A. Because it's very difficult to track in realtime,  
16 where bubbles are moving. It is possible to do with  
17 software, or with individual frame-advancing techniques, but  
18 it would be extremely labor intensive and probably not very  
19 accurate. And so, part of this discovery process, which is  
20 seen in the video which we're discussing, was working out  
21 the very best way to quantify the number of bubbles in the  
22 zone which was being examined at any given time, which is  
23 why snapshots at a pre-determined time were chosen as the  
24 best method to look at a change in bubble concentration in  
25 a certain area over a period of time, over an experimental

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2 run.

3 Q. Were the lighting conditions the same for both the  
4 Bair Hugger and the Hotdog?

5 A. During the experiment?

6 Q. Yes.

7 A. Yes.

8 Q. I'm not sure how to describe the videos that you  
9 were taking, as you're just kind of getting a sense of how  
10 things might work; is that --

11 A. This video was taken while experimenting with -- to  
12 see the effect that could be visualized when using different  
13 equipment in the context that -- that you see here.

14 Q. Whose idea was it to post the videos of you  
15 experimenting with these things?

16 A. I don't remember. It's probably my idea, but I  
17 don't absolutely remember.

18 MR. C. GORDON: Thank you. Nothing further.

19 THE WITNESS: Thank you.

20 THE VIDEOGRAPHER: This is the end of DVD 4 of the  
21 volume 2 of the deposition of Dr. Paul McGovern. Going off  
22 the recording at 5:38. Recording has stopped.

23 (Whereupon, the deposition concluded.)  
24  
25



DR. PAUL MCGOVERN  
CERTIFICATE OF COURT REPORTER

I, Louise Pepper, an Accredited Real-time Reporter, hereby  
certify that the testimony of the witness Paul McGovern in  
the foregoing transcript, numbered pages 233 through 503,  
taken on this 5th day of January, 2017 was recorded by me in  
machine shorthand and was thereafter transcribed by me; and  
that the foregoing transcript is a true and accurate  
verbatim record of the said testimony.

I further certify that I am not a relative, employee,  
counsel or financially involved with any of the parties to  
the within cause, nor am I an employee or relative of any  
counsel for the parties, nor am I in any way interested in  
the outcome of the within cause.

Signed: .....

Name: Louise Pepper

Date: 1-11-2017

## ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS \_\_\_\_ DAY OF \_\_\_\_\_, 2017.

\_\_\_\_\_

(Notary Public) MY COMMISSION EXPIRES: \_\_\_\_\_